

[\*\*\*Hospital letter head\*\*\*]

Local lead investigator: [\*\*\*local\_lead name insert here\*\*\*]

**ISARIC/WHO Clinical Characterisation Protocol (SARI)**

**SARI INTERNAL PILOT STUDY**

**INFORMATION SHEET FOR CONSULTEE**

**16 March 2016. Version 7.3**

We are undertaking a research study involving people with severe acute respiratory infections (SARI). This study is a pilot study, which is a study that will test and rehearse the processes around conducting the full study at a later time.

We are asking you about the participation of an individual who is not able to give consent, because he or she lacks the legal capacity to do so. To help decide if he/she should join the study, we would like to ask your opinion whether or not he/she could be involved.

Before you decide it is important for you to understand why the research is being done and what it would involve for the participant. Please take time to read this information carefully. One of our team will go through the information with you. Please ask us if there is anything that is not clear or if you would like more information and time to decide. Your decision is completely voluntary. The decision you make will not affect the participant's care or treatment in any way.

**What is the study about?**

Infectious diseases affect millions of people around the world every year. Most cases are mild, but some people become very unwell. There is a great deal that we do not understand about existing infections, and new infectious diseases continue to appear. This research study will gain important information about respiratory infections so we can try to find better ways to manage and treat them in the future.

**What will happen if the patient takes part in this study?**

We will collect information from the participant routine clinical records such as participant’s signs and symptoms, medications that he/she is taking, and the results of any blood test and laboratory results that doctors have ordered when hospitalise. This will happen every day while the participant is in hospital.

**What will happen to the information?**

All information about the participant will be kept confidential – anonymised - by those working on this study, the patient name will not be used in any reports about this study. The results of the study will be shared as quickly as possible with health authorities, and doctors to help them treat patients with severe acute respiratory infection.

Anonymised clinical data collected from the participant, will contribute to an annual activation / internal pilot study on SARI. This internal pilot is a multi-centre, prospective, short period incidence observational study of patients with SARI. The activation period will comprise of 7-day cohort study, participants will be admitted in the study who are newly admitted to the hospitals / ICUs at participating sites. All confidential clinical data collected at any other time through the year will be analysed as part of the main clinical characterisation protocol.

The participant’s anonymised information will be shared for the purpose of an international study on Severe Acute Respiratory Infection (SPRINT-SARI).

All information about the participant will be handled in confidence and only the people responsible for his/her care and for this study will know that he/she was part of the study. We will review the participant’s medical records and keep limited information about him/her on a secure file.

The data collected during this study may be looked at by regulatory authorities, authorized individuals from University of Oxford, from the NHS Trust(s) or public health agencies.

The participant’s GP will be informed of he/she is taking part in this study.

**Are there any benefits to taking part in this study?**

There is no benefit to you or the participant personally. The information gained from this study may not be available in time to affect the participant's care. Any results available while the participant is in hospital will already have been given to your treating doctor. The information we learn may help in caring for other patients in the future.

**What are the risks of being in the study?**

There are no additional risks to the health of the patient.

**Who is responsible and what if something goes wrong?**

The research is organised by the University of Oxford with the support of collaborators at this hospital, none of who will benefit financially from the study. It has been reviewed and given a favourable opinion by Oxford C Research Ethics Committee (Ref 13/SC/0149).

The University has arrangements in place to provide for harm arising from participation in the study for which the University is the Research Sponsor. NHS indemnity operates in respect of the clinical treatment with which you are provided. [\*\*\*insert sponsor and contact details\*\*\*]

**Can I request that I be withdrawn from the study at any point?**

Yes, you or the participant can withdraw at any time within this week without giving a reason and without affecting the participant's care. Any data that have not already been analysed can be withdraw anytime this week you or the participant request it.

**What if I have any problems or would like further information about the study?**

If you would like more information about the study you can contact the Lead Investigator in your hospital [\*\*\*local\_lead\*\*\*] or telephone the study coordinator’s office on [\*\*\*phone\_number\*\*\*].