

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

Local lead investigator: [\*\*\*local\_lead\*\*\*]

**ISARIC/WHO Clinical Characterisation Protocol SARI INTERNAL PILOT STUDY**

**INFORMATION SHEET FOR ADULT PATIENT**

**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.

Before you decide it is important for you to understand why the research is being done and what it would involve for you. 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 your 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 I take part in this study?**

We will collect information from your routine clinical records such as your signs and symptoms, medications that you are taking, and the results of any blood test and laboratory results that doctors have ordered when hospitalise. This will happen every day while you are in hospital.

**What will happen to the information?**

All information about you will be kept confidential – anonymised - by those working on this study, your 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 you, 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.

Anonymised data collected will be shared for the purpose of an international study on SARI (SPRINT-SARI)

All information about you will be handled in confidence and only the people responsible for your care and for this study will know that you were a part of the study. We will review your medical records and keep limited information about you 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.

Your GP will be informed of you taking part in this study.

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

There is no benefit to you personally. Any results available while you are 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?**

If you take part in the study and only clinical data is collected from the routine medical records there no additional risk to your health. All information will be used anonymously (no one will know that this information relates to you).

**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 can withdraw at any time within this week without giving a reason and without affecting your care. Any data that have not already been analysed can be withdraw anytime this week you 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\*\*\*].