

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

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

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

**INFORMATION SHEET FOR PARENT/GUARDIAN**

**For parents or guardians of all children and young people under 16 years old, and those aged 16 years to 18 years who are unable to give their own consent for any reason.**

**16 March 2016. Version 7.3**

We are undertaking a research study involving people with severe acute respiratory infections (SARI) with MERS-CoV or Influenza A/H7N9 or A/H5N1 or any other emerging pathogen of public health concern. We are asking you about the participation of a child or young person who is below the legal age at which they can consent to participate in research. We are approaching you because we understand that you are the parent or legal guardian of that child or young person (hereafter referred to as your child). Please declare now if you are not the parent or legal guardian of this child.

Where possible, we will also give your child the opportunity to express his/her views and assent to participate.

Before you decide about your child being involved in this research it is important for you to understand why the research is being done and what it would involve for your child. 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 child'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 new 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 your child’s routine clinical records such as his or her signs and symptoms, medications that he or she is taking, and the results of any blood test and laboratory results that doctors have ordered. This will happen every day while your child is in hospital.

**What will happen to the information?**

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

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

All information about your child will be handled in confidence and only the people responsible for your child’s care and for this study will know that he or she was a part of the study. We will review your child’s medical records and keep limited information about your child on a secure file. All information and samples will be labelled only with a number so that they cannot be directly linked to your child.

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 child’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 to your child. The information gained from this study may not be available in time to affect your child’s care. Any results available while your child is in hospital will be given to his or her 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 risk to the health of your child.

**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 child’s care. Any data that have not already been analysed can be withdraw anytime this week you or your child 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\*\*\*].