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ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections (COVID-19)

INFORMATION SHEET FOR PARENT/GUARDIAN

1st February 2020. Version 3.1

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

Principal Investigator	
Organisation	
Contact details for Principal Investigator	
Study Approval	
NHSRC contact details	

Introduction

We are undertaking a research study involving people with severe acute respiratory infections (SARI) due to emerging pathogens of public health interest, which is why we have approached you and your child.

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

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ISARIC CCP PIS CONSENT FORM PARENT/GUARDIAN 01FEB2020 v3.1

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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 your child's respiratory infection so we can try to find better ways to manage and treat this infection in the future.

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

We will first 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.

If you agree, some samples will be collected which are in addition to what would normally be collected for your child's medical care.

A blood sample might be taken now together with a swab or suction sample from his/her nose and throat, a swab from any infected sites/sores, a sputum sample (if they are coughing up mucus), urine sample and a stool sample (or rectal swab if they are not passing stools).

We will take the same samples again over the next eleven days, on every second day and then every week for as long as your child is unwell up to a maximum of 100 days. We will also invite your child to return to the hospital or clinic in 3 months and 6 months to have a blood sample taken. Each blood sample will take 15mls (3 teaspoons) or less (depending on the patient's weight).

If any other samples **(for example CSF)** are taken from your child for regular care, and if there is leftover sample after the tests requested by your child's doctors are done, we will store the leftover to be tested.

What will happen to the information and samples?

All information about your child will be kept confidential by those working on this study, and your child's name or other identifiers 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.

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest'. **The Malawi**



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Liverpool Wellcome Trust is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you and your medical records, in order to undertake this study. We will keep the minimum personally identifiable information about you indefinitely for safety reasons and because it is a valuable record of this outbreak event. This will be held securely by the scientists running this study under the control of the Liverpool School of Tropical Medicine and Malawi-Liverpool Wellcome Trust

This hospital will use your name and contact details to contact you about the research study, and to oversee the quality of the study. They will keep identifiable information about you from this study according to local policies.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, some of those rights may be limited in order for the research to be reliable and accurate.

We will use the blood samples to look at how the body fights the infection and how treatments given to your child work in their body. If blood cannot be taken from the vein we may use a finger or heel prick. Whilst we currently do not have capacity to do so, we may in future will also use the blood sample to analyse your child's DNA and RNA. We will examine your child's DNA and RNA together with DNA and RNA from many other people to try to find out what makes some people more likely to get an infection. Some of the tests may be done in different countries. DNA contains the genetic information passed on from parents to their children. DNA acts like a recipe holding the instructions telling our bodies how to develop and function. RNA is a copy of DNA naturally made by the body. The researcher will clearly indicate on the consent form if this test is available.

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.

With your permission, we would also like to store your child's samples (for example CSF) and use them for future ethically approved medical research. If you agree to samples being used in future research, your consent form will be retained until the sample has been used up.

The data and samples collected during this study may be looked at by regulatory authorities, authorised individuals from Liverpool School of Tropical Medicine, Malawi Liverpool Wellcome Trust, this hospital, or public health agencies.

Your child's GP will be informed of he/she is taking part in this study.

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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?

Being a part of this study means that if your child takes part in the study and only clinical data is collected from the routine medical records there is a minimum risk, all information will be used anonymously (no one will know that this belonged to your child).

If agreed to collect samples, being part of this study means that more samples will be taken than are needed for normal care. Whenever possible these samples will be taken at the same time as regular samples to reduce the extra procedures. There is a small risk of pain or discomfort when samples are taken.

We are going DNA and RNA (genetic) tests, to understand their influence on the disease caused by this infection. The results of these investigations are unlikely to have any implications for your future care. For these reasons we will not attempt to identify your child or inform your child of any results from DNA and RNA testing.

Who is responsible and what if something goes wrong?

The research is organised by the **Liverpool School of Tropical Medicine and Malawi Liverpool Wellcome Trust** with the support of collaborators at this hospital, none of who will benefit financially from the study.

The **Liverpool School of Tropical Medicine** has arrangements in place to provide for harm arising from participation in the study for which it acts as the Research Sponsor.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact [Name, email, telephone] or you may contact the study Nurse [Name, email, telephone]

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



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Yes, you can withdraw at any time without giving a reason and without affecting your child's care. Any samples that have not already been analysed can be destroyed anytime if you or your child request it.

Will we be compensated for taking part?

You will be compensated for your out of pocket expenses, travel, time spent and burden. You will be paid after each study visit. The payment schedule is based on MK7000 per visit. The number of visits is not fixed. The maximum possible number of visits is 18 over a three-month period. However, we expect that most participants will be requested to complete only two visits for this study. You can withdraw from the study at any time. If you change your mind and do not wish us to commence a new visit we will respect this and not approach you for further visits. Your child will also be offered a token of thanks for their participation. Once your child recovers and returns home, we may contact you to request a visit to check up on your child and take further samples. This visit is your choice, you are free to refuse.

What about future research?

With your consent, we would like to keep your contact details after your participation in this study is complete, so we may inform you of opportunities to participate in future, research. This is entirely optional and agreeing to be contacted also does not oblige you to take part in any future research.

Your contact details would be stored electronically on a secure server and only authorised individuals at Malawi Liverpool Wellcome Trust will have access to it. We will also retain your consent form as long as you are willing to be approached. You can ask us to have your contact details removed from our database at any time.

Who can I contact for more information?

If you want any more information you can speak directly to us or contact by telephone or email (see below). If you want to complain about anything to do with the study, you can do so through the MLW complaints procedure or by contacting the Secretariat of the National Health Science Research Committee (NHSRC) in Lilongwe. The relevant contact details are provided below:



World Health
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Principal Investigator

[Name, email, telephone]

**National Health Science Research
Committee**

[Name, email, telephone]



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Local lead investigator:

**ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections
PARENT/GUARDIAN and PARENTAL AUTHORITY CONSENT FORM (COVID-19)**

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

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Please respond to the following statements by putting your initials or your thumbprint in the spaces provided

Please initial box

I have been consulted about my child's participation in this research project. I have read (or it has been read to me) the information sheet for this study dated 1st February 2020, version 3.1. I understand the information and have had the opportunity to ask questions for clarification.

I understand that his/her participation is voluntary and that I am free to withdraw him/her from the study at any time, without giving any reason and without his/her medical care or rights being affected.

I understand that data will be collected from his/her medical records including medications and laboratory results by study staff during the study. I agree that these individuals may have access to his/her research records and study results.

I understand that data collected during the study may be looked at by regulatory authorities, authorised individuals from **Liverpool School of Tropical Medicine, Malawi Liverpool Wellcome Trust**, this hospital, or public health agencies, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

I understand that if samples are taken laboratory results from samples collected during the study will be reported to study staff. This information may be looked at by regulatory authorities, authorised individuals from **Liverpool School of Tropical Medicine, Malawi Liverpool Wellcome Trust**, this hospital, or public health agencies. I agree that these individuals may have access to my research records and study results.

I understand that his/her information can be collected, analysed, reported and shared with others within and outside **AfricaEurope** as part of this study. I understand that his/her name will not be used and will not be identified.

I understand that his/her samples may be sent elsewhere in the world to be analysed.



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<p>I understand that DNA from his/her blood sample <u>maywill</u> be analysed <u>in the future</u> to determine whether any genetic factors have made him/her susceptible to severe infection.</p> <p>OR IF YOU DO NOT AGREE, TICK HERE <input type="checkbox"/></p>	
<p>I understand that his/her samples, including the participant's DNA and any samples left-over after tests requested by his/her doctor, may be used in additional research in the future, if necessary in different parts of the world, as long as appropriate ethical approval is in place.</p> <p><u>DNA and RNA blood test available (researcher to circle) YES NO</u></p> <p>OR IF YOU DO NOT AGREE, TICK HERE <input type="checkbox"/></p>	
<p>I understand that his/her samples, including the participant's DNA and any samples left-over after tests requested by his/her doctor, may be used in additional research in the future, if necessary in different parts of the world, as long as appropriate ethical approval is in place.</p> <p><u>DNA and RNA blood test available (researcher to circle) YES NO</u></p> <p>OR IF YOU DO NOT AGREE, TICK HERE <input type="checkbox"/></p>	
<p>I understand that I might be contacted directly by the investigators with an invitation for him/her to participate in future research studies.</p> <p>OR IF YOU DO NOT AGREE, TICK HERE <input type="checkbox"/></p>	

Name of parent/guardian/person with parental authority: _____

Relationship to child or young person: _____

Signature: _____ Date: _____



World Health Organization



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OR

Thumbprint if participant cannot write:

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Witness Declaration

If the parent/guardian/person with parental authority cannot read the form: I have no interest or involvement in this research study and I attest that the information concerning this research was accurately read and explained to the parent or person with parental authority in their first language, that they have understood, and that the declaration was freely given by the consultee.

Name of witness: _____ Signature: _____

Date: _____

Person taking consent: _____

(Research team member or health professional trained in taking consent for this study)

Signature: _____ Date: _____

Contact details of participant:

Address: _____ Phone number: _____

Witness Declaration

If the parent/guardian/person with parental authority cannot read the form: I have no interest or involvement in this research study and I attest that the information concerning this research was accurately read and explained to the parent or person with parental authority in their first language, that they have understood, and that the declaration was freely given by the consultee.



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Name of witness: _____ Signature: _____ Date: _____

ASSENT OF COMPETENT YOUNG PEOPLE

Consistent with best practice, and when appropriate, children and young people should be invited to indicate they are willing to participate in this study (assent). Should a competent young person decline to being involved, our study protocol is that the young person's decision should be respected.

Where a child or young person is unable to express their wishes for reasons of acute illness (or otherwise), their views should be sought and recorded at the earliest opportunity once recovered. **Separate assent forms are available for young children (age <12 years) and young people (age 12 to 18 years).**

Thank you for your contribution to this important global research activity.