**ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections**

**INFORMATION SHEET and ASSENT FOR YOUNG PERSON AGE 12 TO 16 YEARS OLD**

We are undertaking a research study involving people with infections due to emerging pathogens (new bugs). We have come you to ask if you would be willing to help us because you have an infection with one of these new bugs.

Before deciding if you want to be involved, it is important for you to understand why this research is being done and what it would involve for you. 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. Agreement to be part of the study is completely voluntary and **will not** affect your care or treatment in any way.

**What is the study about?**

We need to find out more about how infections affect people. By studying your case, we hope to find better ways to diagnose and manage people with this and similar conditions.

**Do I have to take part?**

* It is up to you and your parents/guardians/carer to decide if you should be involved in helping us.
* If you don’t want to be involved, then you don’t have to.
* Either way, your decision will not affect your care and treatments in any way.
* **The choice is yours.**

## Can I withdraw from the study?

Yes, you can withdraw at any time without giving a reason and without affecting your care. Any samples that have not already been analysed can be destroyed, if you wish.

**What will happen if I take part in this study?**

We will collect information from your medical records when you are in hospital, including medication taken and laboratory results. We may collect samples that are extra to what would normally be collected for your normal care in hospital. If samples are taken, each time we will take:

* a blood sample
* a mouth, nose and throat swab (a wipe with a cotton bud or small sponge)
* a swab from any sore skin
* a bit of sputum (chest spit / phlegm) sample
* a urine sample (wee)
* a stool sample (poo) or rectal (bottom) swab.

The amount of blood will be small and will depend on your weight so that we only take a safe amount. The study staff can tell you how much blood will be taken at each visit.

Whenever possible these samples will be taken at the same time as regular samples.

We will take the same samples very soon another two sets during your illness.

If there are any leftovers from other samples taken for your regular care, we will store these leftovers for this research.

When you have recovered and been discharge we will also ask you to return to the hospital to have a blood sample taken.

**What will happen to my information?**

All information about you will be kept private and confidential. Only the people responsible for your care and for this study will know that you were involved in this study.

If you agree, we will also store your data and use it for future approved related medical research. The data collected during this study at any time may be seen and shared with public health agencies.

**What will happen to my samples?**

We will use the samples to discover how you respond to infection, how treatments work and to develop new tests or treatments. As part of this, we will analyse your genetic information (DNA) to discover why people respond differently to infections.

With your permission, we will store your samples and use them for future ethically approved medical studies in the UK or elsewhere. We may use your samples to manufacture tests, treatments or other materials, including commercial products.

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

There are no benefits for you personally. By helping us find out more about why you are ill, we will be able to help look after young people better in the future.

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

The main drawback to you of donating samples is the slight discomfort or pain when samples are taken. We are doing genetic (DNA) tests to understand how your genes affect infections. The results of these tests won’t affect your medical care and we will not tell you of the results from these tests.

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**PARTICIPANT ID: \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_**

**ASSENT OF COMPETENT YOUNG PEOPLE**

**Consistent with best practice, 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**

|  |  |
| --- | --- |
|  | Please tick the box if you agree |
| I have read the leaflet about the study and understand it. |  |
| I know I do not have to take part if I don’t want to and can change my mind. The doctors and nurses will still look after me. |  |
| I do not mind if someone doing research looks at my medical records to see if the study is done in the right way. I know the people who are going the research will keep personal things about me private. |  |
| I agree to take part in the study and to share information from my medical records. |  |
| I agree to take part in the study and to give samples to the study. |  |
| I agree that my samples or materials or data derived from those samples, may be used to **manufacture tests, treatments or other products, including commercial products.** Or if you do not agree to this tick here ❑ |  |
| I agree to let someone talk to me about another study in the future, as this study ends.Or if you do not agree to this tick here ❑ |  |

Name of Young Participant (PLEASE PRINT):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Young Participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_ \_\_ / \_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_

Name of Legal Guardian/Carer (PLEASE PRINT): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Legal Guardian/Carer Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_ \_\_ / \_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_

Name of Person taking assent (PLEASE PRINT):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Signature of person taking assent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_ \_\_ / \_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_

**Witnessed Assent**
*If the assenting person cannot read the form:* I have no interest or involvement in this research study. I attest that the information concerning this research was accurately read and explained to the patient in language they can understand. I attest that assent was freely given by the patient.

Witness name (PLEASE PRINT): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of witness: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_ \_\_ / \_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_

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