**ISARIC/WHO Clinical Characterisation Protocol - IRAS Ref. 126600/ 279826**

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

30th August 2022. Version 10.2  
Local lead investigator: **[\*\*\*local\_investigator\_name\*\*\*]**

We are undertaking a research study involving people with infections due to emerging pathogens (new bugs), or people who have come into contact (exposure) with harmful chemicals or energy. We have come to ask if you would be willing to help us because you may have had an infection or exposure.

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.

**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.

**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. For more information on how we process and protect data, please see the full information sheet or visit [www.isaric4c.net/privacy](http://www.isaric4c.net/privacy).

**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.

**ISARIC/WHO Clinical Characterisation Protocol   
ASSENT OF COMPETENT YOUNG PEOPLE** 30th August 2022. Version 10.2

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

**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: \_\_ \_\_ / \_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_

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

Name of Parent Guardian/Carer (PLEASE PRINT):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact details of Parent/Guardian/Carer

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone Number: \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_

Email of Parent/Guardian/Carer \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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* *or the completed form is contaminated and cannot be removed from the participant’s room:* I have no interest or involvement in this research study. I have been introduced to the participant and identified as a witness to their assent. I attest that the information concerning this research was accurately read and explained to the participant in language they can understand. I attest that assent was freely given by the participant.

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

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