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

**EXTRA CONVALESCENT SAMPLING - INFORMATION SHEET and ASSENT FOR YOUNG PERSON AGE 12 TO 16 YEARS OLD**

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. You had an infection/illness caused by one of these new bugs or exposures and kindly agreed to take part in our research study.

We are now asking if you would be willing to give some extra blood samples for our research.

**What is the study about?**

This form is for young people who have already agreed to take part in the ISARIC/WHO CCP study. We would like to use extra blood samples from children and young people like you, who are now recovered from their illness or exposure.

**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.**

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

If you and your parent/guardian agree, we would use a needle to take some extra blood samples from you. The amount of blood we would take will be calculated based on your child’s weight, at 2.4ml/kg:

* a single extra donation of blood of up to 240mls (less than half a pint) or
* several donations over 16-weeks, up to a total of 470ml (less than one pint).

It may help you to know that a blood donation for a healthy adult (age > 17y and weight >50kg) on one occasion is 470ml and takes 5minutes. The blood sample for this research study is much less, even accounting form your child’s weight.

**What will happen to my samples?**

This extra donation of blood could be used to study immune responses to infection, to develop tests, and set reference standards for blood tests, and to make scientific products or tests.

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

There are no benefits for you personally, but the research may help others in the future.

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

There might be a bit of discomfort during the blood donation. You should not have any side-effects from a blood donation of this size, and you won’t have to change your behavior or activity afterwards.

## 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.

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

**ISARIC/WHO Clinical Characterisation Protocol**

**ASSENT OF COMPETENT YOUNG PEOPLE – EXTRA CONVALESCENT SAMPLING**

30th August 2022. Version 10.2

**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 this part of the study and understand it. |  |
| I know I do not have to take part in this part of the study 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 this part of the study and to give my blood 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 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* *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: \_\_ \_\_ / \_\_ \_\_ \_\_ /\_\_ \_\_ \_\_ \_\_