Local lead investigator: [\*\*\*local\_investigator\_name\*\*\*]

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

**LARGE VOLUME SAMPLING OF CONVALESCENT PATIENTS SUB-STUDY**

**INFORMATION SHEET FOR ADULT PATIENTS**

27th April 2020. Version 3.2

You are being asking to take part in an extra part of this research study involving people who have recovered from an infection due to an emerging pathogen of public health interest.

**What is this study about?**

This form is for patients who have already consented to participate in the ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections and who have recovered from their illness.

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

We would use a needle to obtain a single extra donation of blood of up to 240mls (about half a pint) or several donations over 16-weeks to a maximum volume of 470ml (about one pint). A normal donation to a blood transfusion service is one pint of blood.

**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 products, including commercial products.

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

There is no direct benefit to you, but the research may help others.

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

A blood donation of this size is not expected to have any significant after-effects, and no lifestyle restrictions are required afterwards.

**Who is responsible and what if something goes wrong?**

The research is organised by the [\*\*\*study\_sponsor\*\*\*] with the support of collaborators at this hospital, none of who will benefit financially from the study.

The [\*\*\*study\_sponsor\*\*\*] 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 [\*\*\*local\_investigator\_name\*\*\*] [\*\*\*local\_contact\_details\*\*\*] or you may contact the study coordinator [\*\*\*study coordinator contact details\*\*\*].

**Can I request that I be withdrawn from the study at any point?**

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 anytime you request it.

**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 [\*\*\*hospital\*\*\*] 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.

**What if I** **would like further information about the study?**

If you would like more information about the study you can contact the Local Investigator in your hospital [\*\*\*local\_investigator\_name\*\*\*] or telephone the Local Research office on [\*\*\*local\_contact\_details\*\*\*].

Local lead investigator: [\*\*\*local\_investigator\_name\*\*\*]

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

**LARGE VOLUME SAMPLING OF CONVALESCENT PATIENTS** **SUB-STUDY**

**INFORMED CONSENT FORM FOR ADULT PATIENTS**

27th April 2020. Version 3.2

|  |  |
| --- | --- |
| ***PLEASE MARK YOUR INITIALS AGAINST EACH STATEMENT TO WHICH YOU AGREE:*** |  |
| I have read (or it has been read to me) the information sheet for this sub-study dated 27th April 2020, version 3.2. I understand the information and have had the opportunity to ask questions for clarification. |  |
| I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason and without my medical care or rights being affected. |  |
| I understand that my information can be collected, analysed, reported and shared with others within and outside Europe as part of this study. I understand that my name will not be used and I will not be identified. |  |
| I agree that my samples may be sent elsewhere in the world to be analysed. |  |
| I agree that my GP should be informed of my participation in this study. |  |
| I agree that my samples 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. OR IF YOU DO NOT AGREE, TICK HERE ❑ |  |
| I agree to be contacted directly by the investigators with an invitation to participate in future research studies. OR IF YOU DO NOT AGREE, TICK HERE ❑ |  |

Patient name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_

Person taking consent:

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

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_

**Witnessed Consent**

***If the consenting party 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 patient in language they can understand, and that informed consent was freely given by the patient.

Witness name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

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