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

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

**SERIAL SAMPLING OF CONVALESCENT PATIENTS**

**INFORMATION SHEET FOR ADULT PATIENTS**

27th April 2020. Version 3.2

We are undertaking a research study involving people with infections due to emerging pathogens of public health interest, which is why we have approached you.

You are being asked to take part in a research study involving people with an infection such as the one you have recently recovered from. This information is being given to you to explain why the study is being done, what it involves and why we would like you to take part. Once you have read it, one of our team will go through the information with you. Please ask us if there is anything that is not clear. Agreement to be part of the study is completely voluntary and will not affect your ongoing medical care in any way. You may have already generously participated in a study called the *ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections* whilst you were in hospital – this is part of the same research.

**What is this study about?**

We need to understand more about how the immune system responds to infections such as the one you have just recovered from. This includes finding out which parts of the immune system are involved in making people immune, and how long immunity lasts for.

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

We will collect information about you, including details of the infection you had, the results of tests done while you were unwell, other medical problems you may have and the medicines you take.

We will contact you and ask you to attend a clinic appointment with one of the researchers. At this appointment we will take blood samples (1-2 teaspoons) and a swab from your mouth. We will invite you to return for these samples to be repeated up to every month for up to two years.

**What will happen to the samples and information?**

All information about you will be kept confidential by those working on this study, and your 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 [\*\*\*study\_sponsor\*\*\*] 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 a valuable record of this outbreak event.  This will be held securely by the scientists running this study under the control of the [\*\*\*study\_sponsor\*\*\*].

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.

The samples will be used to study immune responses to infection (which could inform the design of vaccines and medicines), to develop diagnostic tests, and set reference standards for blood tests, and to make medicinal products. Some of the tests may be done in different countries.

All information about you will be handled in confidence and only the people responsible for your care and for this study will know that you were a part of the study. We will review your medical records and keep limited information about you on a secure file. All information and samples will be labelled only with a number so that they cannot be directly linked to you personally.

With your permission, we would also like to store your samples 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 [\*\*\*study\_sponsor\*\*\*], your hospital, or public health agencies.

Your primary care doctor will be informed that you are taking part in this study.

**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?**

If you take part in the study and only clinical data is collected from the routine medical records there is minimum risk, all information will be used anonymously (no one will know that this information relates to you).

If you agree to collect samples, being a 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 risk of pain or discomfort when samples are taken.

**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**

**SERIAL SAMPLING OF CONVALESCENT PATIENTS**

**INFORMED CONSENT FORM FOR ADULT PATIENT**

27th April 2020. Version 3.2

|  |  |
| --- | --- |
|  | **Please initial box** |
| I have read (or it has been read to me) the information sheet for this 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 data will be collected from my medical records, including medications and laboratory results by study staff during the study. I agree that these individuals may have access to my research records and their study results. |  |
| I understand that data collected during the study may be looked at by regulatory authorities, authorised individuals from [\*\*\*study\_sponsor\*\*\*], 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 [\*\*\*study\_sponsor\*\*\*], this hospital, or public health agencies. I agree that these individuals may have access to my research records and study results. |  |
| 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.**