**Coordinating Principal Investigator:** Professor Toby Richards

**Site:** *[Insert Site]*

**Site Principal Investigator:** *[Insert Site PI]*

# ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections (COVID Research Response Trial)

**INFORMATION SHEET FOR ADULT PATIENTS**

ISARIC CCP Version 3.2 27 April 2020 (WA Master Version 6.3, 22 October 2020)

We are undertaking a research study involving people with confirmed or suspected COVID- 19 or Serious Acute Respiratory Infection (SARI), or those with high risk of exposure to the novel coronavirus (e.g. health care workers, household contacts and close contacts), which is why we have approached you.

You are invited to take part in this study but before you decide, it is important for you to understand why the research is being done and what it would involve for you. Please take time to read this information carefully. Please ask us if there is anything that is not clear or if you would like more information and time to decide. Your decision is completely voluntary. The decision you make **will not** affect your care or treatment in any way

# What is the study about?

Infectious diseases affect millions of people around the world every year. Most cases are mild, but some people become very unwell. There is a great deal that we do not understand about existing infections, and new infectious diseases continue to appear. This research will gain important information about your respiratory infection so we can try to find better ways to manage and treat this infection in the future.

As COVID-19 virus only emerged in late 2019 there is not much information about the virus causing it. Through this study we are hoping to gain more information which could help us understand and treat the illness. COVID-19 has impacted all aspects of our lives and we understand that this might be a stressful and confusing time. We are hoping to learn as much as possible about the illness in the hope of finding new treatment options and helping to prepare for other events that might happen like this in the future. Participation in this research is voluntary and you will receive the same care if you decide not to participate.

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

If you agree to be involved in the study we will collect information from your routine clinical records such as your signs and symptoms, medications that you are taking, and the results of any blood test and laboratory results that doctors have ordered.

If you have been admitted to hospital, we will collect this information throughout your stay.

With your permission, we will also collect and store any spare clinical samples that have been taken as part of your normal clinical care. These will be collected after the hospital has finished testing and would otherwise be discarded and destroyed. These ‘leftover’ samples may include (but are not limited to); blood samples, swab or suction samples from your nose and throat, swabs from any infected sites/sores, sputum, urine or stool samples.

If you agree, we may collect additional samples from you for the purpose of laboratory research if you are tested in a COVID testing clinic, admitted to hospital, or after you leave hospital, up to every second day in the first two weeks, and then up to every week, for as long as you are unwell (to a maximum of 100 days after discharge). If you are already having a blood test as part of your care, we will take additional samples at that time, meaning you won’t have an additional needle stick. Otherwise we will take a blood sample from you specifically for the study.

Blood tests carry small risks of pain, discomfort, bruising or infection. When you attend the hospital/clinic, we would like to collect a blood sample of no more than 70ml and a urine sample.

# We may also invite you to return to the hospital or clinic at three to six monthly intervals after discharge to have further samples and survey taken as part of the ISARIC long term follow-up study. For blood samples, we will collect up to 70ml on each occasion (around 5 tablespoons or twice the volume taken in a routine set of blood tests). This will be in one blood sampling episode (one phlebotomy). This will enable a full range of laboratory and experimental tests to be done as detailed below.

# As part of the ISARIC long term follow-up, the survey collects data on demographics, hospital stay and re-admissions, specific physical health consequences, recent febrile illness (fever), new and persistent symptoms, quality of life, breathlessness, difficulties in functioning in day-to-day life, lifestyle and socioeconomic data. This will allow researchers and scientists to explore the long-term physical and psychosocial consequences and immune response over time in COVID-19 post discharge participants.

# If you are a proven COVID-19 participant, we may also invite you to perform an additional Smell Identification Test (UPSIT) at six monthly intervals after discharge, alongside the ISARIC long term follow-up study. The Smell Identification Test is a self-administered 10-15 minute test for indication of smell loss.

# Clinical Trials

Whilst this is not a treatment study, your clinical situation may change and you may become eligible to be included in ‘sister’ clinical trials of different treatment or medication regimes for suspected/proven COVID infection. Current ‘sister’ clinical trials include:

* A Randomised, Embedded, Multi-factorial, Adaptive Platform Trial for Community-Acquired Pneumonia (REMAP-CAP)
* Life AfTER covid-19 (LATER-19): a prospective, longitudinal , cohort study of symptoms, physical function and physiological outcomes
* Australasian COVID-19 Trial (ASCOT)
* Western Australian COVID-19 Immunity Collaboration (WACIC)

Any such opportunity will be discussed in detail with you. Researchers are working together to ‘link’ research projects and may use information from this study to identify suitable participants for clinical trials. Your participation in any clinical trial is voluntary.

**What will happen to my 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, however you will not be personally identifiable in any of this information.

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**, **South Metropolitan Health Service (SMHS)**, 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 a minimum amount of personally identifiable information about you *(e.g. name, date of birth and medical record number)* indefinitely for safety reasons. These identifiers will be kept within the South Metropolitan Health Service (SMHS) according to local policies, and this information can only be accessed by authorised members of the study team. All electronic data will be de-identified and stored at the University of Western Australia (UWA) repository and kept for indefinitely following the completion of the study. All samples will be labelled with only research identifiers for storage (no personal information) and will be kept in University of Western Australia (UWA) storage at the Harry Perkins Institute of Medical Research indefinitely.

The study team may use your information to contact you about this research study (for example, to follow up on any additional care that you received after discharge), and to oversee the quality of the study. The study team may also use your contact details to invite you to participate in further related COVID-19 research studies. Participation in any subsequent COVID-19 research study is entirely voluntary and you do not have to take part in any study that we invite you to.

The information collected about you and the samples collected will be ‘de-identified’. This de-identified data will be used for research now and in the future and may be shared with other scientific organisations such as, (but not exclusively) University of Western Australia and the Australian National Phenome Centre at Murdoch University and researchers working with our team to allow more detailed or complimentary analyses to be done. No health information or samples will be released to a third party unless it is to carry out research that has been approved by a Human Research Ethics Committee, or if disclosure is required by law.

It is possible that authorised representatives of the investigating doctor, the Human Research Ethics Committee and Research Governance Regulatory bodies may require access to the study records to verify study procedures or data but this is not common.

We will abide by State and Federal privacy legislation.

We will use your samples to look at how the body responds to infection and how any treatments given to you are working in your body. By design, the study will include a number of participants who are not positive for COVID-19 and these samples will be used as important disease ‘controls’. We will be undertaking a variety of experimental laboratory investigations, which may include genetic tests. The samples provided will be divided and enable different researcher groups to undertake experimental analysis, so gaining the maximum information at any one point. Your data and samples that are de-identified so the researchers will not know your identity. The samples and data may be shared as part of a national or global research response, some of the tests may be done in different countries.

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

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

There is no benefit to you personally. The information gained from this study may not be available in time to affect your care. Any relevant clinical results and new findings available while you are in hospital will be given to your treating doctor. The information we learn may help in caring for other patients in the future.

# What are the risks of being in the study?

Within the study, the clinical data collected from your routine medical records will be used anonymously (no one will know that this information relates to you). There may be a risk of a data breach. If this happens, SMHS or other health service provider has a data breach response plan, which outlines how they will respond to the data breach. Please ask the study doctor or study nurse if you would like more information about this.

If you consent to additional blood samples for this study, this will mean that more blood will be taken (about twice the volume of a normal set of blood tests) than is needed for normal care. Where possible these samples will be taken at the same time as the normal blood test to reduce the extra procedures. As with all blood tests, there is a small risk of pain, discomfort and infection. However, these risks are minimised by ensuring that qualified, experienced staff collect samples. The volumes of blood taken will be closely monitored and additional research samples will not be taken if there are any clinical concerns.

The results of this research are unlikely to have any direct implications for your future care. For these reasons we would not attempt to identify you or inform you of any results relating to this research.

# Who is responsible and what if something goes wrong?

The research is organised by the **South Metropolitan Health Service (SMHS)** with the support of collaborators, none of whom will benefit financially from the study.

SMHS has arrangements in place to provide for issues arising from participation in the study for which it acts as the Research Sponsor.

This study has been approved by the SMHS Human Research Ethics Committee (HREC). If you have any reservation or complaint about the ethical conduct of this research, and wish to speak to an independent person, you may contact the Manager of the SMHS Research Support and Development Unit via email (SMHS.HREC@health.wa.gov.au) or by phone (Tel. 08 6152 3214). Any issues you raise will be treated in confidence and investigated fully and you will be informed of the outcome.

The study conforms to the principles set out by the National Statement on Ethical Conduct in Research involving Humans and according to Good Clinical Practice Guidelines.

# 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 your decision will not affect your care. We would ask that we can keep existing data and samples for inclusion in the research but similarly you may request that these data are deleted, and samples destroyed.

# What about future research?

We will keep the de-identified data from this study which may be used in similar future research. Any research that this data is used in will be approved by a Human Research Ethics Committee.

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 clinical research. Any future participation in these trials is entirely optional.

Your contact details would be stored electronically on a secure server and only authorised individuals at SMHS 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 Research Team or telephone the Local Research office on 08 6151 1152.

It is anticipated that the results of this study will be published in scientific journals and in other forms. No identifying information will appear in these publications. Once this has happened, if you would like to know about the results then please contact your local clinical contact listed below or the Coordinating Principal Investigator, Professor Toby Richards via email Toby.Richards@health.wa.gov.au or phone 6151 1152.

 **Local clinical contact person**

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| --- | --- |
| Name |  |
| Position |  |
| Telephone |  |
| Email |  |

**Complaints contact person**

|  |  |
| --- | --- |
| Name |  |
| Position |  |
| Telephone |  |
| Email |  |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

|  |  |
| --- | --- |
| Reviewing HREC name | *South Metropolitan Health Service Human Research Ethics Committee* |
| HREC Executive Officer | *Ethics Coordinator*  |
| Telephone | *08 6152 2064* |
| Email | *SMHS.HREC@health.wa.gov.au* |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Local HREC Office contact (Single Site - Research Governance Officer)**

|  |  |
| --- | --- |
| Name |  |
| Position |  |
| Telephone |  |
| Email |  |

**Coordinating Principal Investigator:** Professor Toby Richards

**Site:** *[Insert Site]*

**Site Principal Investigator:** *[Insert Site PI]*

# ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections (COVID – 19) (COVID Research Response Trial)

**INFORMED CONSENT FORM FOR ADULT PATIENTS**

**ISARIC CCP 27 April 2020 Version 3.2 (WA Master Version 6.3 22 October 2020)**

* I have read (or it has been read to me) the information sheet for this study. I understand the information and have had the opportunity to ask questions for clarification.

I understand and agree 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.
* data will be collected from my medical records, including medications and test results by study staff during the study. I agree that these individuals may have access to my medical records and related results.
* data collected during the study (including test results) may be looked at by regulatory authorities, authorised individuals from SMHS, 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.
* my GP will be informed of my participation in this study.
* any samples left-over from routine care tests requested by my doctor may be included in this study.
* additional samples will be taken for the purposes of research.
* I may be invited by the research team to participate in future research studies. I understand that I am under no obligation to take part in any future research studies.
* my deidentified samples and data will be used in COVID-19 related future research projects and may be shared with approved collaborators, subject to Human Research Ethics Committee approvals.

OPTIONAL CONSENT

Do you agree to collection of additional samples and surveys for this study and for future related COVID-19 research? These samples and surveys may be shared with approved collaborators, subject to Human Research Ethics Committee approvals? (this may involve additional blood collection procedures)

(PLEASE TICK BELOW):

YES

NO

Do you agree that my DNA sample, and data generated from my DNA, including the whole sequence of my genome, can be shared anonymously with qualified scientists elsewhere in the world for use in ethically-approved research. I understand that my name will not be used and I will not be identified.

(PLEASE TICK BELOW):

YES

NO

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

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

Person receiving consent:

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

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

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