Participant Information Sheet/Consent Form – *Adult providing own consent*

Title	**Australasian COVID-19 Trial (ASCOT) ADA**ptive **P**latform **T**rial
Short Title	ASCOT ADAPT
Protocol Number	ERM62646-A
Project Sponsor	University of Melbourne
Coordinating Principal Investigators	A/Professor Steven Tong A/Professor Justin Denholm Professor Joshua Davis Dr Susan Morpeth Professor Bala Venkatesh
Site Principal Investigator	*[Principal Investigator]*
Associate Investigators	*[Associate Investigator(s)]*
Location	*[Location]*

We are inviting you to take part in a research study.
Please read this information which will help you decide.

1. Introduction

- We are sorry that you have been diagnosed with Coronavirus Disease 2019 (COVID-19) and admitted to hospital. This must be a very difficult and worrying time for you, but we would like to invite you to participate in a clinical trial that will try to find the most effective treatments for COVID-19. This is a new type of infection and the best treatments are not yet known.
- This Participant Information Sheet tells you about the ASCOT ADAPT research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.
- Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or the doctors who are treating you. If English is not your first language, we can provide an interpreter.
- Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will still receive the best possible care whether or not you take part.
- If you decide you want to take part in the research project, you will be asked to provide consent. By consenting you are telling us that you:
  - Understand what you have read;

- Consent to take part in the research project;
- Consent to have the tests and treatments that are described;
- Consent to the use of your personal and health information as described.

- You will be posted/emailed a copy of this Participant Information and Consent Form to keep.

2. Why are we doing this study?

- The aim of this study is to try to find the most effective treatments for COVID-19. This study might not directly benefit you but may lead to the development of treatment options for patients like you. The trial uses information from patients previously enrolled to increase the likelihood that you will receive treatments that are effective, as explained in more detail in section 3.
- As COVID-19 is a new viral infection, a number of different treatments are being evaluated. COVID-19 is a viral infection and in some people it damages the lungs causing breathing difficulties. It can also cause tiny blood clots in the lungs which can worsen the breathing.
- We are therefore testing 3 different approaches (called "domains") in patients with COVID-19 to see if the treatments are safe and effective:
    - a) antiviral drugs to stop the virus from multiplying;
    - b) antibodies to fight the virus;
    - c) blood thinning drugs called anticoagulants to reduce the risk of clots.
- The domains available at this hospital are described in more detail in Section 5.
- .
- Several treatments may be tested at the same time, in the same patient.
- You may decide to participate in none, one or more than one of these treatment domains. You might not be eligible to participate in all of the domains, if this is the case the study doctor will explain this to you.

3. What will the study involve?

- A member of the study team will discuss the study with you, and you will have the opportunity to ask any questions.
- This research project uses an Adaptive Platform Trial design. The design means that the researchers analyse the results as the trial occurs rather than just at the end. The longer the study continues the more information the researchers can analyse. Although all patients in ASCOT ADAPT are not allocated the same treatment, the study is designed so that as a particular treatment is shown to be better, the number of new patients given that treatment increases.
- During the study you and your doctor will know what treatment you are getting at all times (that is they are not 'blinded'). This means your doctor can stop your study treatment and change other treatments you may be receiving if they need to.
- Your treating doctor believes that all treatment options that will be offered to you are appropriate and suitable for you.
- There are no additional costs for being involved in the research. All medication, tests and medical care required as part of the research project will be provided to you free of charge.
- The study treatment domains described below are available at this hospital: *[Site to delete which treatment domain they are not participating in.]*
    - Treatment Domain A – Antiviral therapy vs standard of care
    - Treatment Domain B – Antibody therapy vs standard of care
    - Treatment Domain C – Anticoagulant therapy with or without aspirin vs standard of care
    - "Standard of care" means the usual treatment that you would be given at this hospital even if you weren't in a trial. This may include inhaled oxygen, close monitoring and drugs already

known to have benefit for some patients, such as dexamethasone or remdesivir. You will receive the standard of care available at this institution.

- You will have time to decide whether you would like to participate in one or more (if available) of these treatment domains or not, and you will be able to discuss with your family if you wish.
- You will then be asked to give your consent. Depending on the infection control measures at the hospital, this consent may be verbal rather than written.
- We will let your GP know that you have decided to take part in this study.
- For each treatment domain, you will be randomly allocated by a computer (like drawing straws) to one of the treatment groups. If you are participating in more than one domain this means you might be given more than one of the study treatments.
- We will collect information recorded as part of your normal care – like your medical history, your demographics (e.g. age, sex and ethnicity), your symptoms, your temperature, oxygen levels, blood tests and any chest X-rays or imaging tests you may have as part of your standard of care. We will not be performing any extra x-rays.

4. What do I have to do?

In hospital

Some of the treatments you receive will be determined by the study but all other treatments and most tests will be those that you would have received anyway. Some additional tests might be required depending on which treatment you are given. These are explained in more detail below. There are also some optional tests that you can choose to have done, but you don't have to. Members of the research team will collect information about you from your medical record and put this de-identified information (details that would be able to identify you will be removed, except for your date of birth and initials) in a database so it can be analysed. The research team will also ask you questions about your breathing.

Following discharge from hospital

You will be contacted by a team member by telephone on day 28 and 90 after starting the study (if you are still in hospital we will collect this information from you in person). If these days fall on the weekend or public holiday we will contact you the next working day. This phone call is to determine how well you are recovering and should take no longer than 5 minutes. We will ask you some questions about your breathing and how you are getting on. If we can't reach you, we will call your GP.

You will be given a participant card with the study team details to keep with you at all times, and you will be able to use the contact details to contact the study team at any time if you have any questions or concerns.

5. What treatments are involved in the trial at this hospital?

[Site to delete treatment domains they are not participating in. For each domain include only information relevant to interventions that your site has selected.]

[Delete following section if site not participating in Domain A – Antivirals]

Domain A - Antiviral drugs that aim to stop the virus from multiplying.

Treatments in this domain

The best therapy and the combination of antiviral drugs which are most effective are not known. At this site, we are studying:

i. **standard of care**
ii. **standard of care plus nafamostat**

All the active therapies are considered experimental but have been carefully assessed by the trial team as among the most promising agents we can offer to patients.

Nafamostat is an agent which may block the entry of SARS-CoV-2 into human cells. Laboratory studies have shown that nafamostat has a strong effect against SARS-CoV-2. It also has blood thinning properties which may help against the clots in the lungs seen in Covid-19. Nafamostat has been safely used in humans for other conditions such as pancreatitis (an inflamed pancreas). Nafamostat may be harmful to the foetus during pregnancy.

Treatment Domain A: Antivirals

Group 1
Standard supportive therapy.

OR

Group 2*
Nafamostat delivered via continuous intravenous infusion, for a maximum of 7 days, in addition to standard of care.

*If you are well enough to be discharged from hospital before day 7 then you will stop taking these treatments when you are discharged

Additional tests and procedures in this domain

- If you are female, we will need to check whether you are pregnant. You may have had a pregnancy test when you were admitted to hospital, if not then we will perform a pregnancy test. If you are pregnant you will not be able to participate in this treatment domain.
- If you are breastfeeding you will not be able to participate in this treatment domain.
- We will monitor standard blood tests for liver function and electrolytes before and during treatment.

[Delete following section if site not participating in Domain B – Antibody therapies]

Domain B - Antibody therapies that aim to boost the level of natural defences to the disease in the blood.

Treatments in this domain

Individuals who recover from COVID-19 develop natural defences to the disease in their blood (called antibodies). Antibodies are found in the part of the blood called plasma. Plasma collected from individuals who have recovered from COVID-19 (called convalescent plasma) will contain antibodies directed against the virus that causes COVID-19. The convalescent plasma is collected by LifeBlood *[or relevant local blood bank organisation]* with the usual safeguards required for all collected blood products. Transfusing convalescent plasma may help patients who are unwell with the infection. At this hospital, we will evaluate:

i. **No antibody therapies (standard care)**
ii. **Convalescent plasma**

The use of convalescent plasma therapy is considered experimental treatment. There is experience using convalescent plasma during previous epidemics and pandemics, such as SARS. Convalescent plasma has been carefully assessed by the trial team as among the most promising antibody therapies we can offer to patients.

Treatment Domain B: Antibody therapies

Group 1

Standard supportive therapy.

OR

Group 2

2 units (250 – 310 mL) of convalescent plasma will be given over a 1-2 day period.

Additional tests and procedures in this domain

- If you are in Group 2, you will need to have a blood test to determine your blood group. This is part of normal care and is required to ensure that the convalescent plasma is compatible with your blood group..
- You will have specific blood tests (to determine the antibody levels) on day 1 before the first transfusion, 24 hours after the second transfusion, and at day 14. If you are discharged before day 14 then the study staff will try to collect the sample on the day you are discharged. These blood samples will be taken whether you are in Group 1 or Group 2. If you consent to us storing your information and samples for use in future research, we will keep any of the sample that is left over after we have tested the antibody levels. We will then be able to share this with other researchers who may be conducting research on COVID-19, related conditions or unrelated research. Your samples will only be shared if the future research has been ethically approved, and the researchers will not receive any identifiable information about you. You do not have to consent to this in order to participate.

[Delete following section if site not participating in Domain C – Anticoagulation]

Domain C - Anticoagulant drugs that aim to prevent blood clots.

Treatments in this domain

All suitable patients who are admitted to hospital with pneumonia, including COVID-19, receive a blood-thinning (anticoagulant) medication (usually a low molecular weight heparin such as enoxaparin) to prevent the development of blood clots in veins (e.g. deep vein thrombosis) and in the lungs, which can be a very serious problem. The usual care is to give a low prophylactic (preventative) dose of the anticoagulant medication. However, patients with COVID-19 appear to have a higher risk of blood clots in the veins as well as blood clots in arteries despite the use of a prophylactic dose of an anticoagulant. Giving a higher dose of an anticoagulant, or adding an antiplatelet medication (such as aspirin) may lead to lower risk of blood clots, but this could also increase the risk of complications caused by excessive bleeding. At this site, the project will evaluate:

i. **Low molecular weight heparin – standard dose**
ii. **Low molecular weight heparin – intermediate dose**
iii. **Low molecular weight heparin – standard dose PLUS aspirin**

The low molecular weight heparin is given as an injection under the skin once a day for 28 days or until you are discharged from hospital, whichever is earlier.

Treatment Domain C: Anticoagulation

Group 1 Standard prophylactic dose of low molecular weight heparin.
OR
Group 2 Intermediate dose of low molecular weight heparin
OR
Group 3 Standard prophylactic dose of low molecular weight heparin AND low dose aspirin

Additional tests and procedures in this domain

There are no additional tests or procedures for this domain.

6. Do I have to take part in this research project?

If you do not want to take part in this research, that's OK. Your decision will not affect the quality of care you receive at *[institution]*. If you take part, you are free to withdraw at any time without giving a reason. Please notify a member of the research team if you wish to withdraw. No further study information will be collected except information related to safety, but we will use the information we have already collected from you.

- If you decide not to take part, you will receive the usual treatments given to patients with COVID-19 at *[institution]*.

7. What are the benefits of taking part?

- You may or may not benefit from the treatment you receive in this study. A benefit of taking part is that you will receive additional testing and monitoring of your condition which may on its own contribute to an improved health outcome.
- This research will improve our knowledge of how to treat COVID-19 and may improve the care of patients with COVID-19 in Australia, New Zealand and across the world.
- There are no costs involved in taking part in this research, and you will not be paid.

8. What are the possible risks and disadvantages of taking part?

Medical treatments often cause side effects. Possible side effects of the treatments included in this trial are listed in Appendix 1. You may have none, some, or all the effects listed and they may be mild, moderate or severe. If you have any of these side effects, and are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

- If a severe side effect occurs, your doctor may need to stop your treatment. He or she will discuss the best way of managing any side effects with you.
- A possible risk is that using the study treatment might mean you have to stop taking one or more of your normal medications, which may cause unrelated conditions you already have to become worse.
- The researchers have thought about how the drugs in different domains might interact with each other and any drugs you are already on. You will only be given study treatments that will not have a high risk of side effects due to your existing medications or study drugs in other domains.
- If you are pregnant, breastfeeding or planning to become pregnant you will only be given treatments that are already used in pregnancy or breastfeeding for other medical conditions, and where safety data about their use is available. If you are pregnant, we will provide additional information about the safety of the treatments offered in this research study for pregnant patients.
- If you are pregnant, we would also like to contact you at 6 weeks, 12 months and 24 months after your baby is born to check on your baby's health and development. We will ask your consent for this on a separate form.
- Your doctor will monitor you closely for any changes caused by the treatment you receive.

9. What will happen to the information collected for this study?

- Your information will be kept strictly confidential. Whilst many researchers will have access to the study data, the study information will be stored securely. Access to your identifiable information will be restricted only to study staff at *[institution],* with the exception of your date of birth and initials which will be entered into the study database.

- The only people allowed to look at information that could identify you will be your doctors, study staff, authorised representatives of the Sponsor and regulatory authorities who may want to check that the study is being carried out correctly.
- Information about you may be obtained from your health records held at this and other health services for the purpose of this research.
- Information collected for the study will be stored securely at *[institution]* for 15 years after the study has ended (as per regulatory requirements) and is the responsibility of the Principal Investigator.
- Information that has had personal identifiers removed (e.g. your name and personal details, with the exception of date of birth and initials) will be replaced with a unique study code. This information will be entered by study staff into a secure password protected web-based database kept on a server in Sydney.
- The University of Melbourne (Sponsor) will be responsible for maintaining the confidentiality of the information in the database.
- This study is being done in several countries including Australia, New Zealand and India. Your de-identified information might be shared with researchers in these other countries and may be combined with information from other studies to allow us to answer questions more quickly. These researchers will not receive any information that could identify you.

[Non-Australian sites remove next bullet point and insert relevant privacy law for your jurisdiction]

- In accordance with relevant Australian and/or [Name of state/territory] privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

10. What will happen to my research samples?

- The results of routine tests taken as part of your usual care will be available to the study team through your hospital medical record.
- With your consent, we would like to store the samples from these routine tests in a central laboratory indefinitely (for example throat/nose swab). This is so they can be used for potential future research about COVID-19 and related conditions, or more broadly for research that may not be related to COVID-19. More information is available at the end of this form. You do not need to agree to the storage of your samples in order to take part in this study.
- Your samples and any paperwork with the samples will not be able to identify you. Your personal information will be removed, with the possible exception of your date of birth.

[For Victoria, SA and Tas keep the next bullet point. All other states remove]

- Samples will be stored in a central laboratory at the Doherty Institute in Melbourne.

[Victoria, SA and Tas remove next bullet point. All other states complete details]

- Samples will be stored in a central laboratory within *[name facility in state]*. The Doherty Institute in Melbourne will supervise the sample storage.
- Samples may also be sent to laboratories overseas to check that the sample results match across all the countries in the study (standardising the test procedures).

11. Could the research study be stopped unexpectedly?

- This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:
  - Unacceptable side effects;

- The drug(s) and/or therapies are shown not to be effective;
- The drug(s) and/or therapies are shown to work and not need further testing.

- If the research is stopped early you will still receive standard supportive therapy.

12. Can I have other treatments during this research?

- Whilst you are in this research, it is possible that you may not be able to take some or all of the medications or treatments you have been taking for other reasons.
- It is important to tell your study doctor and the study staff about any treatments or medications you may be taking.
- Your study doctor will consult with your specialist, before explaining which treatments or medications may need to be stopped or changed for the time you are on the study.

13. Who is organising this study?

- The study is being sponsored by the University of Melbourne.
- The study is being coordinated by the Peter Doherty Institute for Infection and Immunity, a joint venture between the University of Melbourne and Royal Melbourne Hospital (Doherty Institute), as well as the Australasian Society for Infectious Diseases Clinical Research Network and will involve about 2400 participants in over 90 hospitals in Australia, New Zealand and India.
- The study has been funded by a number of organisations including government, charitable donations and through private donations.

14. What happens when the research project ends?

- At the end of the trial, we can send you a summary of the research results on request.

15. Complaints and compensation

- If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible who will help arrange any medical treatment you may need. If you are eligible for Medicare, you can receive any medical treatment required to treat the injuries free of charge, as a public patient in any Australian public hospital.
- In the event of loss or injury caused by taking part in the trial, the Sponsor has agreed to pay for hospitalisation and any medication costs.
- In addition, you may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor). You do not give up any legal rights to compensation by participating in this study.

16. Who has reviewed the research project?

- All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC).

- The ethical aspects of this research project have been approved by the *[Site to insert name of approving HREC]*. This project will be carried out according to the *National Statement on Ethical*

Conduct in Human Research (2018). This statement has been developed to protect the interests of people who take part in research studies.

17. Further information and who to contact

- The person you may need to contact will depend on your query. If you want more information about this project, you can contact the lead study doctors: Associate Professor Steven Tong on (03) 9342 9406, Associate Professor Justin Denholm on justin.denholm@mh.org.au or Professor Joshua Davis on joshua.davis@menzies.edu.au.

For questions about your medical care or about taking part in the trial at this hospital:

Clinical contact person

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

The HREC that has approved this research and HREC Executive Officer details

Reviewing HREC name	*[Name of HREC]*
HREC Executive Officer	*[Contact person]*
Telephone	*[Phone number]*
Email	*[Email address]*

Site - Research Governance Officer

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

Appendix 1: Potential side effects

The tables below outline the possible side effects for each type of treatment and how likely they are to occur.

- Common = (>10%) or more than 10 people out of every 100 people will report this side effect;
  Uncommon = (1-10%) or 1 to 10 people out of every 100 people will report this side effect;
  Rare = (0.1-1%) or 1 in 1,000 to 1 in 100 people will report this side effect;
  Very rare = (<0.1%) or less than 1 in 1,000 people will report this side effect.

[Delete if site not participating in Domain A]

Domain A – Antiviral drugs

Side effect	How often is it likely to occur	Comment
Nafamostat		
Pain/redness at the site of infusion	Very rare	
Elevated liver enzymes	Rare	Unknown whether truly related to nafamostat because liver is not involved in nafamostat metabolism
Elevated potassium	Uncommon	Due to effects of nafamostat on potassium excretion by the kidneys
Decreased sodium	Rare	Due to effects of nafamostat on sodium retention by the kidneys
Bleeding	Theoretical risk, frequency unknown	Increased bleeding has not been seen in use of nafamostat for other conditions but is a theoretical risk given how it works.
Birth defects	Unknown, risk based on animal studies	May harm the fetus following exposure of nafamostat.

[Delete if site not participating in Domain B]

Domain B – Antibody therapy

Side effect	How often is it likely to occur	Comment
Rash and itch	Uncommon	Normally self resolves, sometimes antihistamines may be given
Fever	Rare	Normally, self resolves, sometimes antihistamines may be given
Severe allergic reactions	Very rare	Like anaphylaxis and may cause difficulties with breathing and drop in blood pressure
Fluid overload causing difficulty in breathing	Rare	More likely with larger volumes of blood product

Lung injury causing difficulty breathing	Very rare	Risk is reduced by only using plasma from male donors
Infection from the plasma donor	Very rare	All convalescent plasma is stringently screened for infections as per any blood product

- Further details about adverse effects from plasma transfusion can be found at https://transfusion.com.au/adverse_transfusion_reactions/classification_and_incidence.

[Delete if site not participating in Domain C]

Domain C – Anticoagulant and Antiplatelet drugs

Side effect	How often is it likely to occur	Comment
Low molecular weight heparin		
Major bleeding	Rare	Most bleeding is minor bleeding, but rarely major bleeding may occur that requires transfusion or an intervention to stop the bleeding
Bruising at injection site and other minor bleeding	Common	Usually minor bruising that does not require any intervention
Low platelet count, sometimes associated with blood clots (heparin-induced thrombocytopenia– HIT)	Rare	Treatment is with a non-heparin anticoagulant until platelet count returns to normal, and longer if associated with a blood clot
Allergic reactions	Uncommon	Usually mild allergic reaction that self resolves, sometimes requires treatment e.g. with anti-histamine
Abnormal liver function tests	Uncommon	Usually mild that self resolves and doesn't require any specific treatment
Aspirin		
Major bleeding	Rare	Most bleeding is minor bleeding
Gastrointestinal side effects (e.g. nausea, vomiting, heartburn)	Uncommon	Usually mild
Allergic reactions	Uncommon	Usually mild that does not require intervention

Insert Header with institution's name or institution's letterhead

Consent Form - Adult providing own consent

Title	**Australasian COVID-19 Trial (ASCOT) ADA**ptive **P**latform **T**rial
Short Title	ASCOT ADAPT
Protocol Number	ERM62646-A
Project Sponsor	University of Melbourne
Coordinating Principal Investigators	A/Professor Steven Tong A/Professor Justin Denholm Professor Joshua Davis Dr Susan Morpeth Professor Bala Venkatesh
Site Principal Investigator	*[Principal Investigator]*
Associate Investigator(s)	*[Associate Investigator(s)]*
Location	*[Location]*

Verbal Declaration by Participant

- I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.
- I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[institution]* concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.
- I consent to participating in **Treatment Domain A Antivirals** ☐ Yes ☐ No
  [delete if hospital site not participating in Treatment Domain A]
- I consent to participating in **Treatment Domain B Antibodies** ☐ Yes ☐ No
  [delete if hospital site not participating in Treatment Domain B]
- I consent to participating in **Treatment Domain C Anticoagulation** ☐ Yes ☐ No
  [delete if hospital site not participating in Treatment Domain C]
- I consent to the storage and use of my collected information, including samples collected for the purpose of assessing the interventions in ASCOT ADAPT (e.g. serum samples, nose and throat swabs) as described in this document, for
  Other research study that is closely related to this research project ☐ Yes ☐ No
  Any future research ☐ Yes ☐ No
- I understand that I can withdraw my consent to participate in the research project by filling in a "Withdrawal of Consent" form, or by telling a study team member.
- I would like a copy of the study results when they become available. ☐ Yes ☐ No

Name of Participant (please print) _____

Signature of participant *(if able to provide written consent)* _____

Email address *(if participant would like study results emailed):* _____

Name of Interpreter if used (please print) _____

Signature _____ Date _____

Identification card number: _____

☐ Consent was obtained using interpretation via telephone.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

A copy of this consent will be sent/emailed to the participant

[Site to delete this section if not participating in optional biological sampling]

Insert Header with institution's name or institution's letterhead

Additional consent for collection, storage and use of biological samples - Adult providing own consent

As an optional part of the study, we are asking for your consent to collect additional study samples from you (e.g. blood, nose/throat swabs, or stool) . You do not have to agree to this and will still be able to participate in the study without providing the extra samples. With your permission: *[Include only those samples that are collected at the site. Delete all bullet points that are not relevant]*

- We will collect a research specific stool sample on day 1.
- You will have extra blood tests on days 1, 3, 7 and 14 while you are in hospital only. Depending on the treatment group you are enrolled in, additional blood samples for monitoring may be required. If you are discharged before day 14 these blood samples will be taken on the day you are discharged. These blood tests are for research purposes only.
- You will have a nose and throat swab similar to the one you originally had to test for COVID-19, on days 1, 3 and 7.
- With your consent, research samples obtained as part of this study will be stored and used for potential future research about COVID-19 and related conditions, as well as for research that is not related to COVID-19.
- It is not possible to predict exactly what specialised laboratory tests will be performed on your samples. Tests will focus mainly on the immune system and responses, as well as studying the virus that caused your COVID-19 illness. In future your samples may be used to study other things that we have not thought of yet.
- One sample may be used for genetic research that involves ''whole genome* sequencing''. It will look for the areas of your genome that may play a role in the development of COVID-19.

  *The genome is the body's "instruction manual". It contains all the information needed to make you, run you and repair you. You have a copy in nearly every cell in your body. It is made up of a chemical code called DNA, and there are 3 billion letters of code.
- This research is looking at all the letters of this code (whole genome sequencing). The research will look at finding the genetic areas which are susceptible to COVID-19 when compared with healthy people.
- Your sample will be one of many and the genetic research is limited. It will not provide any information about your future health or risk of having children with a genetic disorder, or information that may be relevant to the health of family members who are not part of this study.
- You will not be given your individual research results. This research study is not intended to provide you or your treating doctor with clinical information, or impact on your clinical treatment other than that related to COVID-19.

Consent to collection, storage and use of samples

I consent to the storage and use of biological samples taken from me for use, as described above, for

- COVID related research studies ☐ Yes ☐ No
- Any future research ☐ Yes ☐ No

In respect to the storage and use of my DNA samples, I give permission for the use of my DNA samples for the purpose of

- COVID related research studies ☐ Yes ☐ No
- Any future research ☐ Yes ☐ No

Name of Participant (please print) _____

Signature of participant *(if able to provide written consent)* _____

Name of Interpreter if used (please print) _____

Signature _____ Date _____

Identification card number: _____

☐ Consent was obtained using interpretation via telephone.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

A copy of this consent will be sent/emailed to the participant