Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*

Title	ATHENA Covid-19 Genomics
Short Title	COVID-OZGenetics
Protocol Number	*2020001490*
Project Sponsor	*University of Queensland*
Coordinating Principal Investigator	Professor Naomi Wray
Co Investigator(s)	Dr Loic Yengo Dr Kirsty Short Dr Larissa Labzin Professor Kim Greaves Professor Matt Trau
Location	Institute for Molecular Biosciences University of Queensland

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in the *ATHENA CV19-G research project.* This is because *you have or have had a positive test for the COVID-19 infection or believe you have had COVID-19.* The purpose of this research is to determine if there are genetic and/or environmental factors that cause some people to experience more severe COVID-19 infection symptoms than others.

This Participant Information Sheet/Consent Form tells you about this research project. It explains what is involved. Understanding 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 this research project with a relative, friend or local doctor.

Participation in this research is voluntary. If you do not wish to take part, you do not have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in this research project, you will be asked to sign the consent form. By signing the form, you are telling us that you:
• Understand what you have read
• Consent to take part in this research project
• Consent to the tests and research that are described
• Consent to the use of your personal and health information as described

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

COVID-19 is part of the Coronavirus family that causes respiratory infections. The virus was first reported in December 2019 and as of March 2020 the World Health Organisation classified COVID-19 as a global pandemic. Transmission primarily occurs through droplets of saliva, or discharge from the nose when an infected individual coughs or sneezes. The severity of symptoms can range from no symptoms to severe symptoms requiring hospitalisation.

The purpose of this research is to determine if there is a genetic and/or environmental link in why some people experience severe symptoms and others have mild symptoms of COVID-19 infection. This information may lead to new testing methods, and/or treatments that could benefit future generations.

3 What does participation in this research involve?

You will be asked to consent agreeing to complete two questionnaires, provide blood samples and to grant access to your clinical data in relation to your symptoms, treatment, and recovery of COVID-19 infection.

- **Consent**

If you agree to participate you will be asked to sign the consent form prior to any data and blood collection.

Questionnaires

COVID-19 Symptom Questionnaire You will be asked a series of questions about the symptoms and their severity of your COVID-19 infection. We will also ask you about why you were tested or not tested and the treatment you received. You will receive a unique research participant number and a link via email to complete the questionnaire online. This will take approximately 10 minutes to complete. Should you wish to complete a paper copy, we can provide this to you, or a member of the research team can administer this over the phone. You will be asked to complete this questionnaire immediately after consenting (baseline) and a follow up symptom questionnaire at 3months, 6months and 12months.

Lifestyle and Environmental Risk Factors Questionnaire
You will be asked questions about your ancestry, family, occupation, residential history, diet, physical activity, lifestyle behaviours e.g. smoking, alcohol and exposure to chemicals and pesticides.

There are some questions regarding use of prescription and illicit drug as well as medical history information including questions pertaining to sexually transmitted diseases (STDs). Some questions are only relevant to some people, for example questions relating to menstruation and pregnancy.

You will receive a unique research participant number and a link via email to complete the questionnaire online. This will take approximately 40 minutes to complete, and you will only need to complete this once. If you are unable to complete questionnaires online, the research team will offer you to complete a paper copy or by telephone interview. You are not obliged to answer any questions that make you feel uncomfortable or questions you would prefer not to answer. You can skip over them.

- **Biological Sample**

  We will ask you to donate a sample of blood (30mL) after consenting and at follow up at 3months, 6months and 12months as this aspect of the study involves the genetic analysis of samples donated by participants. DNA will be obtained from the blood sample you provide and used to look for regions on the genome which could be involved in how the body responds to a CV19 infection. Other parts of your blood sample such as plasma and serum will also be collected and stored for use in biomarker studies.

  Blood samples collected from you will be used to generate genetic information, this may include sequencing your genome. This information will be screened to look for variations; firstly, between people who all have had a COVID-19 diagnosis and their range of symptoms and secondly compare differences between people that may contribute to the differences in severity of COVID-19 symptoms.

  We know that research progresses much faster if other researchers can also study your data. Other researchers may obtain access to and use your de-identified health information, genetic information and biological samples for COVID-19 and other health research. Researchers not at UQ who may want to use your data or samples have to apply to the Principal Investigators of this project. Your data can only be obtained and used by researchers who have their study approved by a Human Research Ethics Committee. Any researchers who wish to use your data must also agree to protect your privacy.

  As part of this project, we may share your genetic information collected from your samples with international consortiums also researching the COVID-19 virus. Only your genetic information, NOT your identifying information will be sent.

  If you do not wish to provide a blood sample, you will be offered the option to provide a saliva sample as an alternative. Although we can obtain DNA from your saliva sample the quality and quantity of DNA from blood is much higher. We also collect plasma and serum from your blood sample which can be used to study and detect circulating biomarkers that are found to be associated with a COVID-19 infection or symptoms you may have experienced as part of your COVID-19 infection.

  You will be provided with a biological sample collection kit (specific for the type of sample you are willing to donate), along with instructions on how to collect and handle your sample. This will be sent to your nominated address. Blood samples you donate can be collected at a phlebotomy centre of choice (e.g. QML Pathology, SNP). Saliva samples can be collected by you in your own home. Return your biological sample using the prepaid lab mailer kit provided, to Institute for Molecular Biosciences, UQ via Australia Post.

  We do recommend that you discuss your participation in this project with your family and GP before consenting.

- **Access to medical records**

  We would like to obtain information about your treatment, hospitalisation and recovery from your medical records with your consent.

  Your medical information will be linked via a unique research code to your biological sample and self-report questionnaire data. Your name, DOB and contact details will be stored separately to your biological sample and questionnaire data. Only the lead investigators and authorised research staff will have access to individual identity information and only where it is required.

4 Additional costs & reimbursement

There are no costs associated with participating in this research project. On completion of the baseline questionnaires and once we have received your blood sample you will be sent an $80 gift card to your nominated address for reimbursement of your time, travel, parking and other expenses that you may have incurred as a result of participating.

On receipt of the follow up questionnaires and blood samples you will receive a gift card for $40 for reimbursement of costs associated with participating in the follow up time points.

5 What do I have to do?

There are no restrictions in lifestyle, dietary or types of treatment you receive throughout the study. If you are involved in another research study, we ask you to advise the research coordinator.

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

Participation in any study is voluntary. If you do not wish to take part, you **do not** have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage without consequences.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with The University of Queensland.

7 What are the possible benefits of taking part?

There will be no clear benefit to you from your participation in this research. However, we hope that the results generated from this work may benefit society by the discovery of information on how genetics play a part in COVID-19 infection, improve clinical diagnostics, treatments, and care.

The University of Queensland, Queensland Health or another company may benefit financially from the outcomes of research projects that have used your health information in approved research projects.

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

There are risks and discomforts associated with every research project. They deserve careful thought and consideration.

- Having a blood sample taken may cause you some discomfort or bruising. Sometimes, the blood vessel may swell, or blood may clot in the blood vessel, or the spot from which tissue is taken could become inflamed. Rarely, there could be a minor infection or bleeding. If this happens, it can be easily treated.

- Discomfort: The online questionnaires will ask personal questions that you may find sensitive, or make you feel uncomfortable depending on your personal experience. The questions are all optional and at any time you may skip a question or stop immediately. You are under no obligation to answer every question.

- Breach of confidentiality: This may occur as a result of many different people being involved in the collection of data for this study. Individuals not directly part of this study may see your collected data, particularly if some parts of your participation have coincided

with another research project or clinical appointment.

- Genetic Information:
    - Someone could trace the coded information in a scientific database back to you and your participation in this study. Even without your name or other identifiers, your genetic information is unique to you (like a fingerprint). We think the risk of this happening is very low.

      Generating genetic information using the DNA obtained from your sample raises some important issues. Standard practice for genomic research is not to return research findings to participants. As a research team and as part of our analysis of your data we may report information relating to the primary aims of this project back to your General Practitioner if they are proven to be valid and of health significance to you.

      Results that could be of significance to you will need to be repeated and verified. This will involve having a new biological sample taken and having it tested in an accredited clinical testing laboratory. This is standard practice for research participants receiving information about their genome. Before the research findings are validated, you will be counseled about the possible issues that might arise and the risks involved for you and potentially your family. This is especially important for individuals who are found to have a genetic mutation that is associated with an increased risk of developing a disease such as cancer or heart disease. If you agree to providing a new sample for the purpose of clinical genetic testing, this will be performed as part of the clinical care being provided by your General Practitioner.

    - Participation in this genetic study may have an impact on your access to health, disability, or life insurance if information about your participation, or information collected through your participation becomes part of your medical record. Insurance companies may consider participation in this genetic study “high-risk” believing that is implies there is a family history of a genetic condition. If you are self-employed, or if you apply for a position in which the employer screens employees for health or life insurance purposes, you may have problems with access to health or life insurance. It is also possible you may be refused employment or be terminated from your current employment if the employer’s insurance carrier believes you are a high risk for certain genetic disorders. This could happen if you choose to discuss your participation with your doctor. This would place the information in your medical records, an area to which insurance companies routinely have access.

    - Participants in this or any related studies cannot claim ownership rights to any medical or scientific product that results from research with their samples. Research results about you as an individual will not be available to you, your GP nor will it be recorded in your health records.

9 What will happen to my blood samples?

You will be asked to provide additional consent for the collection of your blood during this research project. Collection of these samples is a main part of the project as the analysis of these samples is what forms the basis of the research.

The blood sample will be sent to The Institute for Molecular Bioscience at The University of Queensland for the purpose of generating genomic information.

The blood samples will be assigned a unique research code and the laboratory team who process your sample **do not** have access to any confidential information provided in questionnaires or medical information. Similarly, individuals of the research team who may be involved in your recruitment **do not** have access to your genetic information. The separation of information helps to maintain your confidentiality and privacy. The samples will be re-identifiable only by the Principal Investigator or authorised member of the laboratory research team

Samples of your blood for the purpose of this research project will be processed and stored at UQ. The University of Queensland will not knowingly transfer your samples to anyone who has expressed intent to sell the samples.

We are seeking your consent to store your sample for future use in research projects that are an extension of this research project. Alternatively, we may use your sample for future research that may or may not be related to the original research project.

We know that research progresses faster if other researchers can also access your de identified data and samples. With the continuous advancement of technology and scientific knowledge and with your consent your sample could you be useful in future unknown research.

You have the option to consent how your sample will be used. Your participation is voluntary and the length of your involvement in this study is at your discretion.

10 What if I withdraw from this research project?

If you decide to withdraw from this research project, you can withdraw from the study at any time. Your decision to participate or not will not affect your current or future relationship with The University of Queensland nor current or future relationship with your health care professional.

If you wish to withdraw your consent during the research project, no additional personal information from you will be collected. Although, information already collected will be retained to ensure that the results of the study can be measured properly and to comply with law. You should be aware that data collected and used in analyses up to the time you withdraw will form part of the research project results.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

The University of Queensland and research staff are bound to undertake research in accordance with the Australian Privacy Principles (2014), the Australian Code of the Responsible Conduct of Research and NHMRC National Guidelines for the Ethical Conduct of Human Research (2007) updated 2018.

By signing the consent form, you consent to relevant research staff collecting and using personal information about you for the research project. The information will always be disclosed to them in a de-identified form, that is without your: name, initials, date of birth, address or contact details being attached to it. Any information obtained in connection with this research project that can identify you will remain confidential.

Your de-identified personal health information, questionnaire responses and biological samples may be given to authorised researchers for HREC approved projects. Your data may be inspected by relevant research oversight authorities for verifying research procedures and data. All personal information is stored on secure servers behind the UQ security firewall.

Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

12 Who is organising and funding the research?

This research project is being conducted by Professor Naomi Wray and is being funded by NHMRC program grant.

You will not benefit financially from your involvement in this research project. In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to UQ, there will be no financial benefit to you or your family from these discoveries.

13 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 HREC of UQ.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) updated 2018. This statement has been developed to protect the interests of people who agree to participate in human research studies.

14 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want further information concerning this project or if you have any medical problems which may be related to your involvement in the project, you can contact:

Research Project Manager contact

Name	Ms Anjali Henders
Position	Study Manager
Telephone	07 3346 2089
Email	a.henders@uq.edu.au

For matters relating to the online questionnaire troubleshooting or queries on biological samples, you can contact the PCTG research staff:

Research staff contact

Name	PCTG research staff
Telephone	07 3346 2089
Email	hsu-projects@uq.edu.au

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:

External contact

Reviewing HREC name	University of Queensland HREC
HREC Executive Officer	Ethics Coordinator
Telephone	07 3365 3924/ 07 34431656
Email	humanethics@research.uq.edu.au

Consent Form - *Adult providing own consent*

Title	ATHENA Covid-19 Genomics (COVID-OZGenetics)
Protocol Number	*2020001490*
Coordinating Principal Investigator/	Professor Naomi Wray
Co Investigator(s)	Dr Loic Yengo Dr Kirsty Short Dr Larissa Labzin Professor Kim Greaves Professor Matt Trau
Location	Institute for Molecular Biosciences, UQ The University of Queensland

Declaration by Participant

I have read the Participant Information Sheet, or someone has read it to me in a language that I understand. I agree to participate and provide information and biological samples as required. I consent to participate under the following conditions:

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 have agreed to provide biological samples and their use has been explained and accepted by me including the generation of genetic information by sequencing my genome.

I understand that all data pertaining to me including my DNA I have provided (but **not** my name or address) may be made available to researchers in the future, some of whom may have commercial interests. I donate my biological sample freely for these purposes and waive any claim to commercial rights arising from this work.

I understand that I will be given a signed copy of this document to keep.

I give permission for my doctors, other health professionals, hospitals or clinical laboratories to release information to *The University of Queensland* concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

Please select only one option:

- ○ I request that genetic research findings of validated health significance identified in my DNA be shared with my clinician and understand that validation of these will require an additional biological sample to be provided.

OR

- ○ I **do not** want genetic research findings of validated health significance identified in my DNA to be shared with my clinician. I understand this means I **will not** receive any information

through my participation in this project of genetic research findings that may be of importance to me and/or my family.

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

1. this research project only Yes ☐ No ☐
2. this research project and any closely related future research projects Yes ☐ No ☐
3. future research projects that may or may not be related to this research project Yes ☐ No ☐

I agree to be recontacted for future HREC approved research projects Yes ☐ No ☐

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants <u>unable</u> to read the information and consent form

See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9, witness * required
Witness to the informed consent process
Name (please print) _____
Signature _____ Date _____
* Witness is <u>not</u> to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may <u>not</u> act as a witness to the consent process. Witness must be 18 years or older.

<u>Declaration by Researcher</u>†

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 Investigator/
Delegated research personnel†
(please print) _____

Signature _____ Date _____

† A delegated research personnel will have undergone training in genomic research consent.

Note: All parties signing the consent section must date their own signature.

Participant ID:

PARTICIPANT CONSENT FORM

Consent to release of Medicare and/or Pharmaceutical Benefits Scheme (PBS) claims information for the purposes of ATHENA COVID-19 Genomics Study (COVID-OZGenetics) HREC 2020001490

Important Information

Complete this form to request the release of personal Medicare claims information and/or PBS claims information to the ATHENA COVID-19 Genomics Study

Any changes to this form must be initialled by the signatory. Incomplete forms may result in the study not being provided with your information.

By signing this form, I acknowledge that I have been fully informed and have been provided with information about this study. I have been given an opportunity to ask questions and understand the possibilities of disclosures of my personal information.

PARTICIPANT DETAILS

1. Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Family name: _____ First given name: _____

Other given name (s): _____

Date of birth: DD/MM/YYYY

2. Medicare card number: _____

3. Permanent address:

_____

Postal address (if different to above):

_____

AUTHORISATION

4. I authorise the Department of Human Services to provide my:

- ☐ Medicare claims history OR
- ☐ PBS claims history OR
- ☐ Address details OR
- ☐ Medicare/PBS claims history and address details

for the period* from the date I participate DD/MM/YYYY to 31/12/2035 the ATHENA COVID-19 Genomics Study.

*Note: The Department of Human Services can only extract 4.5 years of data (prior to the date of extraction), The consent period above may result in multiple extractions.

DECLARATION
I declare that the information on this form is true and correct.

5. Signed: _____ (participant's signature) Dated: (DD/MM/YYYY)

OR

6. Signed by _____ (full name) _____ (signature) on behalf of participant

Dated: DD/MM/YYYY

☐ Power of attorney** ☐ Guardianship order**

** Please attach supporting evidence

APP 5 – PRIVACY NOTICE

Your personal information is protected by law, including the Privacy Act 1988, and is collected by the Australian Government Department of Human Services. The collection of your personal information by the department is necessary for administering requests for statistical and other data.

Your information may be used by the department or given to other parties for the purposes of research, investigation or where you have agreed, or it is required or authorised by law.

You can get more information about the way in which the Department of Human Services will manage your personal information, including our privacy policy at humanservices.gov.au/privacy or by requesting a copy from the department.

Power of attorney – A power of attorney is a document that appoints a person to act on behalf of another person who grants that power. In particular, an enduring power of attorney allows the appointed person to act on behalf of another person even when that person has become mentally incapacitated. The powers under a power of attorney may be unlimited or limited to specific acts.

Guardianship order – A Guardianship order is an order made by a Guardianship Board/Tribunal that appoints a guardian to make decisions for another person. A Guardianship order may be expressed broadly or limited to particular aspects of the care of another person.

A sample of the information that may be included in your Medicare claims history:

Date of service	Date of Processing	Item number	Item description	Provider charge	Schedule Fee	Benefit paid	Patient out of pocket	Hospital indicator
20/04/09	03/05/09	00023	Level B consultation	$38.30	$34.30	$34.30	$4.00	N
22/06/09	23/06/09	11700	ECG	$29.50	$29.50	$29.50		N

A sample of the information that may be included in your PBS claims history:

Date of supply	Date of prescribing	PBS item code	Item description	Patient category	Patient contribution (this includes under copayment amounts**)	Net Benefit (this includes under copayment amounts**)	ATC Code	ATC Name
06/03/09	01/03/09	03133X	Oxazepham Tablet 30 mg	Concessional Ordinary	$5.30	$25.55	N05 B A 04	Oxazepam
04/07/09	28/05/09	03161J	Diazepam Tablet 2 mg	General Ordinary	$30.85		N05 B A 01	Diazepam

Form for Withdrawal of Participation - *Adult providing own consent*

Title	ATHENA Covid-19 Genomics
Short Title	COVID-OZGenetics
Protocol Number	*2020001490*
Project Sponsor	*University of Queensland*
Principal Investigator **Co Investigator**	Professor Naomi Wray Dr Loic Yengo Dr Kirsty Short Dr Larissa Labzin Professor Kim Greaves Professor Matt Trau
Location	Institute for Molecular Biosciences, UQ

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *University of Queensland*

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Delegated research personnel
† (please print) _____

Signature _____ Date _____

† A senior member of the research team or delegate must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.