Queensland Government

The ATHENA COVID-19 Study. Data Linkage study of outcomes in patients with COVID-19 in Queensland

Recovered Patients: Adult Participant Information and Consent Form for linking General Practice records and for Future Coronavirus-Related Unspecified Non-Interventional Research.

Title	**The ATHENA COVID-19 STUDY: Data Linkage study of outcomes in patients with COVID-19 in Queensland**
Short Title	**ATHENA COVID-19 Study**
Protocol Number	**HREC Approval GC 63555**
Project Sponsor	**Queensland Health**
Coordinating Principal Investigator/ Principal Investigator	**Professor Kim Greaves**
Contact Email	**AthenaCV19@health.qld.gov.au**
Location	**Queensland Department of Health**

How can you help us with research in Coronavirus?
Coronavirus is a new disease. We currently have limited knowledge on how it spreads and how it can be treated. Queensland Health thinks it is very important that we can do research to help find ways to prevent and treat it, for example, by trying to develop vaccines.

To help our community, Queensland Health believes it is important to be able to use your health information that your General Practitioner (GP) and Queensland Health holds or has access to, for Coronavirus related future research.

Queensland Health seeks your consent for the ATHENA COVID-19 Study to obtain a one-time only copy of your complete GP health record and link it with your Queensland Health records. Queensland Health also seeks your consent to recontact you in the future. Your consent will allow authorised researchers to use your health information for Coronavirus related research in the future. We are currently not able to specify all studies because researchers haven't yet defined or thought of it. Any research undertaken would first have to be approved by a registered Human Research Ethics Committee. All information shared with researchers will be de-identified. De-identification means removing identifying information from the data and samples i.e. you will be known to these researchers by a code and not by your name. Participation in this study is entirely voluntary.

Before making a decision about taking part, it is important you understand what some terms mean.
In this document:

- when we refer to a *"Health Service"* we are referring to the particular "*Hospital and Health Service*" within Queensland Health, where you are being, or have been, treated. "*Hospital and Health Service*" has the same meaning as in the *Hospital and Health Boards Act 2011* (Qld).
- when we refer to a '*GP'*, we are referring to the general practice(s) where you are seen or have been seen by a general practitioner.

- when we refer to "*researchers*" we are referring to people from both within Queensland Health or outside of it, such as a university, who are authorised to perform a research study by way of a research project approved by a registered Human Research Ethics Committee in Australia;
- when we refer to "your health record" we are referring to the part of the Health Service and record containing your health information that we can access at the Health Service.
- when we refer to *"health information"* we are referring to the health information that Health Services routinely collect, have access to, analyse and store, about the health of patients to deliver services, care and treatment to them. It can include health information provided to Queensland Health and Health Services by GPs, registries and other providers of healthcare such as private hospitals.
- when we refer to *"personal information"* we mean information about you that can be used to identify you.

What is included in your health information?

Your health information may include medical and personal information (including information about past medical history including mental health, medications, family history, personal details such as your name, age, address, date of birth and Medicare number, test results (including blood tests, weight, height and blood pressure readings) Your Health information may also include information about any psychiatric/psychological issues, sexual health issues, behaviours and drug use or notes from clinicians. If you decide to give Queensland Health your consent, your health information used for **approved coronavirus research** will not include any information that may also be able to identify people other than you, such as your family members, as part of your family and social medical history.
Your health information will only be requested from your GP's electronic record if you consent to participate.

What kind of research is involved?

If you decide to give Queensland Health your consent, your health information will be used by authorised researchers in the future for research related to Coronavirus but that we are currently not able to specify because researchers haven't yet defined or thought of it. This type of consent is known as unspecified consent, or broad consent.

How is future research approved?

To protect your interests and your health information, before your health information is given to authorised researchers for research projects, a Human Research Ethics Committee registered with the National Health and Medical Research Council (which is Australia's peak research body) must first carefully examine each research project and approve that they consider it to be ethically acceptable in accordance with the *National Statement on Ethical Conduct in Human Research (2007) – Updated 2018.*

What does participation in the research involve?

Your consent to participate in this study is entirely voluntary. If you give your consent, Queensland Health will request a copy of your health record from your nominated GP. This will be stored securely with your health information kept within Queensland Health. Your de-identified health information will only be shared with authorised researchers for ethically approved research projects and you will not be required to do anything more.
Each approved research project has different rules and procedures regarding how authorised researchers can use and disclose your health information under what conditions they can do so.
Results from research using your health information will not be given to you or your doctor or recorded in your health records. There will be no cost to you, and you will not be paid for the use of your health

information. Participants in this or any other authorised project cannot claim ownership rights to any medical or scientific product that results from their information.

How do we protect your privacy?
The collection, storage, use and disclosure of your health information, your access to it and your ability to have it amended, is governed by the Health Service's privacy policies.

Will your identity be published?
No. Any published research papers, including any published results of the research, will not be capable of identifying you.

Why are we are requesting verbal consent?
You are able to provide your consent verbally for this study rather than in writing. This is because verbal consent is the most efficient way to rapidly contact the large numbers of patients who have had COVID-19 and then analyse the results as quickly as possible. One of our project team members will telephone you to discuss the project and whether you wish to participate. If you agree to take part, we will ask your permission to record a certain part of the telephone conversation to document this. If you prefer, you can give written consent by signing this Patient Information and Consent Form physically or electronically and returning it to us via a supplied self-addressed envelope or through electronic means.

Who will have access to your health information?
Your health information shared with authorised researchers for approved projects may be inspected by relevant research oversight authorities and authorised representatives of the Health Service for verifying research procedures and data. Additionally, your health information may be used or disclosed if the use or disclosure is authorised or required by law as set out in the Health Services Privacy policies.

What is the most common way your health information will be used by researchers?
Approved future unspecified Coronavirus related research may include collecting and reviewing your health information. If your health information is shared with an authorised researcher for approved Coronavirus-related research, that researcher may also then share your health information with other authorised researchers for approved Coronavirus-related research. Any health information shared with other researchers outside of Queensland Health will be de-identified as much as standard best practice makes possible and be handled in strict accordance with their privacy policies. De-identification means removing identifying information from the data i.e. you will be known to these researchers by a code and not by your name.

What happens if you do not give your consent?
Participation in this study is entirely voluntary. If you do not consent, this consent form cannot be used to make your health information available to authorised researchers for approved unspecified future Coronavirus-related research. Your care and treatment and your relationships with the Health Service and those treating you will not be affected by your decision to participate or not. You do not need to provide any reasons for not giving your consent.
Please note that even if you do not consent there are other lawful ways that researchers can gain access to your health information for use in research **without** your consent. For example, in Queensland, researchers can apply to be given health information held by a health agency through the research provisions (Chapter 6, Part 4) of the *Public Health Act 2005* (Qld).

How long will your consent last?
Unless you withdraw your consent while you are alive, your consent will continue for as long as the Queensland Health holds your health record. For example, Queensland Health will hold your health record in accordance with its *Clinical Records Management* policies (available at the Queensland Health policy website at QH Policy Website which includes the *Health Sector (Clinical Records) Retention and Disposal Schedule* (Queensland Disposal Authority Number [QDAN] 683)

What if I change my mind?
You can withdraw your consent for your health record to be used under this consent form at any time by contacting the ATHENA COVID-19 Coordination Centre by email ATHENACV19@health.qld.gov.au. A *Withdrawal of Consent* form will be provided for completion, signature, which can be returned to the Coordination Centre. *Withdrawal of Consent* forms and instructions for submitting them are also available for download from the Queensland Health ATHENA COVID-19 website at https://www.health.qld.gov.au/research-reports/research-projects/athena-covid-19, You do not need to provide any reasons for withdrawing your consent.

Your health information will not be available for any approved future unspecified Coronavirus-related research after the date you withdraw your consent. However, if your health information has already been used in approved research projects, you cannot withdraw your consent for your health information that was used in those projects. No one else can withdraw your consent on your behalf, even after your death.

Further contact with you
The aim of allowing further contact with you is to help researchers recruit participants for ethically approved future Coronavirus-related research projects. By this, we mean you are giving consent for a member of the ATHENA COVID-19 project team to contact you in the future to discuss potential participation in such projects. You will only be contacted by a member of the ATHENA COVID-19 project team by choosing "YES" for re-contact when you sign the consent form.

Are there any direct benefits to you?
Assisting health research can benefit everyone by improving the delivery of care and increasing our understanding of human health and wellbeing, diseases, their treatments and side effects. However, there will be no direct benefits to you specifically from your participation in approved future unspecified research, including financially, regardless of the outcomes of the research projects. Queensland Health or a company or a university may benefit financially from the outcomes of research projects that have used your health information in approved research projects.

What are the possible risks and disadvantages of taking part?
There is a potential risk to your privacy and health information security if there is a breach of our privacy and data security practices. This has a low likelihood of occurring as we are required to operate within strict standards for the transfer of information from your GP to Queensland Health. The ATHENA COVID-19 follows standard policies and procedures for electronic security as per the health service, Queensland Health and the Department of Health (State). If you require further information regarding data security and privacy, we can provide further information to you upon request.
For some participants, being asked to recall the events of when they were infected might trigger emotional distress. If this occurs, we do have mental health support processes in place to help. This includes, where appropriate and with your permission, contacting your general practitioner and/or treating physician, and the local mental health support services.

How are research discoveries dealt with?

Information released to researchers is de-identified and all efforts will be made in the design of research to limit the possibility of identifiable significant findings. However, consenting to participate in the Study means you are consenting to be notified of incidental findings that are linked to you that have health implications as per the criteria described below.

During research, discoveries could be made that have serious and important health consequences for you or your family. When undertaking the research, researchers may find that you or your family members might be at risk of a serious health condition. However, it is very rare for a serious finding to be discovered and, as information is de-identified, it is further unlikely to be linked to you. However, if this were to occur, the study may refer the matter to a clinical expert, who will evaluate the result to determine whether it is a serious and significant finding and whether it should be returned to you for further action.

Only identified findings that meet each of the following criteria will be returned:

- Significant: The finding indicates a life-threatening health condition.
- Clinically actionable: Specific established therapeutic interventions or other available actions.
- Confirmed: The finding has been checked and confirmed as accurate and/or valid, as far as reasonably possible in a research context.

If you are not contacted about a finding, it does not mean you don't have any health issues. It is important to continue your regular health check-ups with your family doctor and other health professionals. If a serious finding is made and you are told about it, it might have an effect on any insurance you apply for in the future (for example life insurance or income protection) and we therefore suggest you get advice from your chosen insurer.

Declaration

I have read this *Patient Information and Consent Form,* or someone has read it to me in a language that I understand. I understand the information in this *Patient Information and Consent Form,* and I have had the opportunity to ask questions of clinicians or a trained project team researcher about this consent who have answered those questions to my satisfaction.

I understand the purpose of my consent is to make my health information available for use by researchers in research projects approved by a registered Human Research Ethics Committee at the Health Service for a broad range of future unspecified health research related to Coronavirus.

Consent

I freely and voluntarily give consent for authorised researchers to use my health for research related to the Coronavirus in the future that is approved by a registered Human Research Ethics Committee, but that Queensland Health is currently not able to specify.

I also agree that my health information used for those projects may be inspected by relevant authorities and authorised representatives of the Health Service to verify the research procedures and data of the approved research projects.

I agree that Queensland Health or a company or a university may benefit financially from the outcomes of the approved research projects that have used my health information.

I understand that I am free to withdraw my consent at any time without affecting my future health care but that if I do not withdraw my consent it will continue, even after I have died, for as long as the Queensland Health holds my health record in accordance with the Health Service *Clinical Records Management* policies.

Name of Participant: (please print) _____

Signature of Participant: _____ Date: _____

I consent to be re-contacted about possible participation in future COVID-19 related studies.

Yes ☐ No ☐

Only complete Witness box below if the Participant is unable to read,

***If an* interpreter is used, the interpreter must not be the witness. The witness must be 18 years or older.**

Name of Witness: Click or tap here to enter text.

Signature of Witness: Click or tap here to enter text. Date: Click or tap to enter a date.

If the participant is unable to read, then, by signing and dating the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant and that informed consent was freely given by the participant.

Declaration by Clinician/Trained Project Researcher

I have given a verbal explanation of the approved research project; its procedures and risks and I believe that the participant has understood that explanation. I have assessed the participant's capacity to consent in accordance with the Health Service policies and I believe that, at the time of this declaration, the participant has capacity to give the consent given by the participant and documented above.

Name of Clinician/
Trained Project Researcher: _____
PLEASE PRINT

Signature: _____ Date: _____

Record of contact and verbal consent obtained from patient

On this date: at this time: and

PICF with this confirmation forward to patient by email/post on

On this date at this time

By, Consenters Name: _____

PLEASE PRINT

Role: _____

Signature: _____ Recorded Verbal Consent YES ☐ NO ☐

NB: All signature boxes will be converted to fillable forms.

The ATHENA COVID-19 STUDY: Data Linkage study of outcomes in patients with COVID-19 in Queensland

ADULT- Withdrawal of Consent Form for Future Unspecified Non-Interventional Coronavirus Related Research

Purpose of this document

This document should be used if:
1) you previously verbally consented to/or signed the *Participant Information and Consent Form for linking General practice records in the ATHENA COVID-19 STUDY and for Future Unspecified Non-Interventional Coronavirus Related Research.* By signing that form you provided consent for authorised researchers to use your health information for future unspecified research related to Coronavirus approved by a Human Research Ethics Committee and may have consented to be recontacted in the future about other Coronavirus related research.
2) you now wish to withdraw consent to be re-contacted in the future and/or
3) You may wish to withdraw your consent for your health information to be used **in any** future Coronavirus related research.

Research Projects that will not be affected by this document

Your withdrawal of consent via this document will not affect the use of your health information:
a) in research projects for which you had provided consent via a means other than the *Participant Information and Consent Form for your child under 18 years old to participate with Future Unspecified Non-Interventional Coronavirus or Related Research*.
b) in research projects for which researchers have used lawful means to gain access to your health information for use in research without your consent. For example, in Queensland, researchers can apply to be given health information held by a health agency through the research provisions (Chapter 6, Part 4) of the *Public Health Act 2005* (Qld).
c) provided to a researcher for use in approved research after you signed the *Participant Information and Consent Form for linking General practice records in the ATHENA COVID-19 STUDY and for Future Unspecified Non-Interventional Coronavirus Related Research* but prior to your withdrawal of consent.

Who can sign this document?

This document must be signed by the individual who signed the *Participant Information and Consent Form for linking General practice records in the ATHENA COVID-19 STUDY and for Future Unspecified Non-Interventional Coronavirus Related Research*. No-one else can withdraw consent on your behalf, even after your death.

Explanation of terms used in this document

In this document:

- when we refer to a *"Health service"* we are referring to the particular "*Hospital and Health Service*" where you are being, or have been, treated. "*Hospital and Health Service*" has the same meaning as in the *Hospital and Health Boards Act 2011* (Qld).
- when we refer to "*researchers*" we are referring to people from both within Queensland Health or outside of it who are authorised to perform a research study by way of a Research project approved by a registered Human Research Ethics Committee in Australia.
- when we refer to "*your health record*" we are referring to the part of the Health Service record containing your health information that we can access at the Health Service.

- when we refer to a General Practice (GP) we are referring to the general practice(s) where you are being or have been seen by a GP.
- when we refer to *"health information"* we are referring to the information that Health Services routinely collect, analyse and store about the health of patients to deliver services, care and treatment to them. It can include health information provided to the Health Service from General Practitioners and other providers for example from GPs, registries and other providers of healthcare such as private hospitals.

Withdrawal of Consent

I hereby withdraw consent for the ATHENA COVID-19 STUDY and for authorised researchers to use my health information for unspecified coronavirus related research in the future, and/or to be recontacted by a member of the ATHENA COVID-19 Study. Please complete option boxes prior to signing.

I understand that my care and treatment and my relationships with this or other health facilities and those treating me will not be affected by my decision to withdraw my consent.

I also understand and acknowledge that if my health information has already been provided to authorised researchers in accordance with the consent I provided by signing the Adult- *Participant Information and Consent Form for linking General practice records in the ATHENA COVID-19 STUDY and for Future Unspecified Non-Interventional Coronavirus Related Research*, I cannot withdraw my consent for my health information that was used in those projects. However, I understand that my health information will not be provided for any future research projects related to the 'The ATHENA COVID-19 STUDY: Data Linkage study of outcomes in patients with COVID-19 in Queensland', without my consent (except as permitted by law).

Contact regarding participation in future research

I hereby withdraw consent to being contacted by a member of the ATHENA COVID-19 project team about participation in future COVID-19 related research. Yes:☐ No:☐

I withdraw my consent for any of my health information to be used in future Coronavirus related research Yes: ☐ No:☐

Name of Participant: Click or tap here to enter text.

Signature:Click or tap here to enter text. Date:Click or tap to enter a date.

If the participant is unable to read, then, by signing and dating this form, the witness attests that the information in this form and any other written information was accurately explained to, and apparently understood by, the participant and that an informed decision was freely made by the participant.

After completing and signing this form, please email this page to ATHENACV19@health.qld.gov.au or return via post in the self-addressed envelope.

NB: Only complete the Witness statement box if the participant is unable to read. The witness must not be a researcher connected to a project relevant to this form. If an interpreter is used, the interpreter must not be the witness. The witness must be 18 years or older.

Name of Witness to Participant: Click or tap here to enter text. Signature: Click or tap here to enter text. Date:Click or tap to enter a date.

NB: All signature boxes will be converted to fillable forms.