Participant Information and Consent Form

The content of this participant information and consent form will be replicated on the QoVAX SET webpage page. A REDcap form will capture and store consent to take part in this study. A copy of this participant information and the individual's consent will be sent electronically (by the person's preferred email or text) to the participant for their own records.

QoVAX SET Program –Pilot
Adult providing own consent

Title	Queensland COVID-19 vaccine (QoVAX) Safety and Efficacy Trial (SET) – Pilot Study
Coordinating Principal Investigator	Professor Janet Davies on behalf of the investigator team
Locations	STARS and Royal Brisbane and Women's Hospital (RBWH), Metro North Health Cairns and Hinterland Hospital and Health Services Vaccine Command Centre Metro South Health Service Vaccine Command Centre

Part 1 What does my participation involve?

1 Introduction

As someone who has registered for a COVID-19 vaccine given by one of the above Queensland Health vaccination centres, you are invited to take part in the QoVAX SET Pilot Study.

Being involved in this research study means that you are personally contributing to increasing our understanding of the impacts of, and responses to, the COVID-19 vaccine now and in the future.

You will be asked to complete surveys, and donate some saliva and blood. You will also provide us with information about how you are feeling or any reactions you may have to the vaccine. We will then be able to measure how your immune system responds to the vaccine, and the factors that affect that immune response.

This Participant Information <Sheet/Webpage> and electronic Consent Form tells you about this research project and what is involved so you can decide if it is something you want to be part of.

Please read this information carefully and ask questions in person or by contacting the research team (QoVAXSETProgram@health.qld.gov.au) about anything that you don't understand or want to know more about.

Participation in this research is voluntary, and it will not affect you getting the vaccine.

2 What is the purpose of the QoVAX SET Pilot study?

This QoVAX SET Pilot study aims to increase our understanding of how well the vaccine is working and how we can refine the scope of the QoVAX SET research studies. The study results will help Queensland Health manage the public health response to COVID-19, including this vaccination program.

The data and knowledge gained from this QoVAX SET Pilot Study will:
1. Provide more information for health professionals about the benefits of the vaccine for different people in the community whose immune system may be affected by other factors such as health conditions or medication use, and
2. Help health professionals and leaders make more informed decisions related to delivering health services when international borders open.

3 What does participation in the QoVAX SET Pilot study involve?

Being involved in this study means that you are personally contributing to us having an increased understanding of the impacts of, and responses to, the COVID-19 vaccine now and in the future.

You will be asked to complete a survey and provide a saliva and some blood samples. There will be three study visits in the pilot study:

1. Before your first COVID-19 vaccine dose,
2. Before your second COVID-19 vaccine dose, and
3. One month after the second COVID-19 dose.

If you receive the AstraZeneca vaccine we will contact you three weeks after your first vaccine to ask you to go the QoVAX SET webpage and fill in the post vaccine questionnaire to capture information on whether you had any reactions to the vaccine.

To protect your privacy, your information will be stored securely with a unique QoVAX SET study code in the study Biobank. Samples collected will be de-identified for both testing and storage. Information will be used for future health surveillance.

The blood and saliva samples collected will be used for a variety of tests to look at markers of immune response, including immune cell functions and genetic analyses for gene variants or combinations of gene variants that may be associated with certain immune outcomes. The genetic analysis will include DNA sequencing of an array of small parts of your genome, or for some we will do whole genome sequencing that gives fully detailed genetic information. The purpose of these genetic tests and the survey questions about you are to help find any factors or combinations of factors that may be associated with how people's immune system responds to the vaccine.

The answers you will be asked to give in the survey will include:
1) Information about you, your health background and lifestyle, and
2) Information about your COVID-19 vaccine experiences, including any adverse reactions.

This information along with any reported adverse reactions, other health information (e.g. hospital records, COVID-19 test results), and test results from this research study, will all be linked securely in a research databank created for this project inside eHealth Queensland.

Samples and data generated will be analysed and used for research by skilled university researchers who are part of this study team, to learn more about how safe and effective the COVID-19 vaccines are in our community.

The research outcomes are expected to help in the public health planning and clinical care of people who may get the COVID-19 virus. The QoVAX SET Pilot outcomes will also help in

design of a larger QoVAX SET study. When available, we will share summarised reports on the QoVAX SET study on a public webpage.

There are no costs associated with taking part in this research project, nor will you be paid. We recognise there will be some inconvenience to you in having to return to a vaccine centre or pathology collection centre to give samples one month after your second vaccine dose. You would not normally need to come back at this time. For the research team, this collection is the most important sample collection time to achieve the main goal of the QoVAX SET Pilot research because one month after your second vaccine dose is when your immune system should show the most response to the vaccine.

The QoVAX SET team may invite you to continue to be involved in longer-term follow up study to see how long people stay immune to the COVID-19 virus after vaccination.

4 What do I have to do?

At the time of having the COVID-19 vaccine, if possible, you will be asked to meet the QoVAX SET study coordinator 30 minutes *before your vaccine appointment time*.

At each QoVAX SET Pilot study visit, you will be asked to help in three ways:

Survey
The Pre-vaccine survey will take about 15 minutes to complete. Three weeks after each of the vaccine doses you will be asked to complete the Post-vaccine survey will take you about 5 - 10 minutes to complete.

The post vaccine surveys can be filled independently on your own smart phone, tablet or computer by clicking a link that will be sent to you.

Blood sample
A small amount of blood will be collected (40 mL – around 2 and a half tablespoons) from a vein in your arm. This would be similar to any blood test you may have.

Saliva sample
Saliva will be collected by placing a swab under your tongue.

5 Other relevant information about the research project

Individuals who are invited to participate are people who are eligible for the COVID-19 vaccine and registered for a COVID-19 vaccination at one of the QoVAX SET Pilot study sites.

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

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your eligibility for getting the COVID-19 vaccination.

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.

Should you change your mind and choose to withdraw from the QoVAX SET Pilot study you can do so at any time. Your biological specimens will be destroyed, and your information deleted, making it no longer available for research after that date.

7 What are the possible benefits of taking part?

The results of this research project will not provide you with any direct benefit because the tests we will do are for research use only. We do not know yet how well these tests will indicate the effectiveness of response to the COVID-19 virus.

This research will provide an understanding of how effective the COVID-19 vaccines are in the Queensland population and how the immune system responds over time. This will help planning for COVID-19 vaccinations and inform decisions around border controls and other public health measures in place to protect Queenslanders.

The research will also provide more information for health professionals about the benefits of the vaccine for different people in the community whose immune system may be affected by other factors such as, health conditions or medication use.

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

There will be no significant risk to you from the saliva or blood test, as the amount of blood taken will be small. In some cases, minor bruising, bleeding and pain can occur.

In rare cases, immune function or genetic analysis results are found which could affect your health or your families' health. If this is the case, then every possible effort will be made to pass this information back to you via medical doctors in the QoVAX SET team who specialise in clinical immunology and clinical genomics, or who are connected with the study site where you participated.

Statutory or contractual duties *may* then require you to disclose that information to third parties (for example, insurance companies or employers), particularly where the results provide meaningful information about your health prospects. However, 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.

If you have concerns about this occurring, please discuss with an investigator prior to completing the consent form.

9 What will happen to my test samples?

We will store your biological samples (saliva and blood) and clinical data in the study biobank and linked databank for future use in COVID-19 related research projects including investigations of associated health conditions.

10 What is the potential impact on my family if I take part?

You will not be asked to give us detailed information about your relatives. If the research finds that one of your family members may be at risk of a life-threatening or serious illness for which treatment is available or pending, this information may, in limited circumstances and in accordance with privacy legislation, be offered to you by one of the study doctors.

11 Will I be given the results of the research project?

You will not be given your test results because the research is early stage and we don't know how the tests will relate to COVID-19 vaccine outcomes.

To protect your privacy, any results about you will be combined with information about other people in the study, and any information in research reports and publications will not be able to be traced back to you.

When available, you will be able to see a summary of the results on the QoVAX SET public webpage.

12 Will drug or biotechnology companies be able to use my sample for profit in the future?

This research is not sponsored by drug or biotechnology companies. We will not share raw data or samples collected for this QoVAX SET Pilot study with biotechnology companies without your consent.

There is the possibility that the research findings may have implications for commercially viable technology, tests or treatments. However, you will not be able to claim financial benefit from any discoveries arising from the use of your biological samples/clinical data.

13 Biobanking (Long term storage of samples) and databanking

To get the most benefit from doing this QoVAX SET Pilot, samples and data that have been collected and generated, will be made available to other eligible researchers for future COVID-19 research studies.

The research team seeks your permission to store your samples, which are not used immediately during the core part of this research, and the health and research data linked to them, in the QoVAX Queensland Digitally Integrated Biobank for COVID-19 , managed by Pathology Queensland.

Saving of samples in this biobank will allow other doctors and scientists to use your samples and health information to learn about response to the COVID-19 vaccine.

If you consent to participate in this study, then you consent to your samples being stored and used by approved investigators in future COVID-19 related research. Any future research projects will be subject to review and approval by a Human Research Ethics Committee (HREC) and the QoVAX SET Program team.

14 What are the possible benefits of banking my blood samples?

There is no direct benefit to you. Other people might benefit if researchers learn more by using your samples to answer further research questions about COVID-19. There is no extra physical risk to you as part of the research.

Your samples and research test results will be stored as a "re-identifiable" sample. This means that your sample will be identifiable by a code; it can be identified as yours even though the biobank and laboratory researchers do not know your identity.

You can have your samples and stored data removed, destroyed or returned to you by contacting the research team. However, any scientific data which has already been derived from analysis of your samples, or any specimen/data which has been provided to collaborators, before this time will not be able to be destroyed or returned.

15 Will I be informed of future research or results of research using my samples?

We may contact you to ask you to take part in further research, such as the longer term stages of this study, but you will be under no obligation to do so.

If we do need to contact you, we will use the contact details you have provided as part of the consent form and survey. We will also ask for current and alternative contact details (e.g. phone and email) in the event that your details change.

16 QoVAX SET Pilot study databanking of Health Information

We will not use your personal health information for research into unrelated research projects without the permission of a HREC and without your consent. Once all personal identification is removed, the information might be used for COVID-19 related research purposes without asking you. We may share only de-identified data with collaborators as part of this QoVAX SET Pilot study, or for future COVID-19 related health research.

If we want to use your samples or information for research other than for COVID-19, then the research team will contact you and ask for your consent.

Results of the research project may be presented in public talks or written articles but participant information will be de-identified.

The information we collect and store in the QoVAX SET databank for COVID-19 for this QoVAX SET Pilot study includes:
1. your consent form,
2. demographic information (age, gender),
3. details of your routinely collected vaccine and public health service information,
4. your survey responses, and
5. all results of tests done as part of this research project.

All information collected via the surveys, any linked health information, and research test results including immune response results and genetic results, will be stored securely and de-identified, as part of the QoVAX SET databank for use in COVID-19 related research.

Part 2 How is the research project being conducted?

17 What will happen to information about me?

Only the primary investigators will be able to access your personal details; the other investigators and collaborators will use your unique study code. Your information will only be used for the purpose of this research project and the QoVAX Queensland Digitally Integrated Biobank for COVID-19, HREC approved future projects. Your information will only be disclosed with your permission, except as required by law.

In any reports and/or presentations, information will be provided in such a way that you cannot be identified.

In accordance with relevant Queensland privacy and other relevant laws, you have the right to request access to your information collected and stored by the study team (QoVAXSETprogram@health.qld.gov.au). You also have the right to request that any information with which you disagree be corrected.

18 Complaints

If you suffer any injuries as a result of this research project, you should contact the study team as soon as possible. If you have any concerns or questions regarding the QoVAX SET Pilot study or your participation please contact us at QoVAXSETProgram@health.qld.gov.au

19 Who has reviewed the research project?

The QoVAX SET Pilot study has been reviewed by an independent group of people as part of the Royal Brisbane and Women's Hospital HREC.

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 take part in human research studies.

20 Further information and who to contact

If you want any further information about this project, you can contact the following people:

Study contact person

Name	Professor Janet Davies
Position	Program Director
Telephone	07 3647 8007
Email	QoVAXSETprogram@health.qld.gov.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	
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 approving this research and HREC Executive Officer details

Reviewing HREC name	Royal Brisbane and Women's Hospital HREC
HREC Executive Officer	The Coordinator
Telephone	07 3647 1007
Email	RBWH-Ethics@health.qld.gov.au

Investigators

Table 1. QoVax SET chief investigator team

Name	***Position***	***Team Role***
Prof. Janet Davies	Director, QOVAX SET Program Metro North Health	Principal Coordinating Investigator
Dr Krispin Hajkowicz	Metro North Health	Investigator
Dr Peter Bourke	Cairns Hinterland Hospital and Health Service	Investigator
Dr Andrew Henderson	Metro South Health	Investigator
Dr Nic Waddell	Coordinator of the Cancer Program, Head of Medical Genomics Laboratory, QIMR Berghofer	Investigator
Associate Professor Tony Kenna	Centre Immunology and Infection Control, Queensland University of Technology	Investigator
Dr Kirsty Short	Institute of Molecular Biology, The University of Queensland	Investigator
Prof. Michael Kimlin	Professor Epidemiology and Child Health, Mater Research Institute, and QUT	Investigator
Dr Andrew Redmond	Infectious Diseases Physician, Royal Brisbane and Women's Hospital	Investigator
Rebecca Gregory	Scientific Program Lead – QoVAX SET, Metro North Health	Associate Investigator

Consent Form

Title	*QoVAX SET Program – Pilot Phase*
Coordinating Principal Investigator	*Professor Janet Davies*
Locations	*STARS – Surgical Treatment and Rehabilitation Service, and Kippa Ring Community Vaccination Clinic, 488 Elizabeth Avenue, Kippa Ring* *Metro North Health Vaccine Command Centre* *Cairns and Hinterland Hospital and Health Services Vaccine Command Centre* *Metro South Health Services Vaccine Command Centre*

Declarations of the Participant

I have read the Participant Information, or someone has read it to me in a language that I understand.	Yes/No
I understand the purposes, what is involved, and risks for this research project. I have had a chance to ask questions and I am satisfied with the answers I have been given.	Yes/No
I freely agree to take part in this research project and I understand that I am free to withdraw at any time during the project without affecting my future health care.	Yes/No
I understand that I will be sent a copy of my consent and participant information to keep.	Yes/No
I give permission for the storage and use of my biological samples and health information for the purpose of this research project, and COVID-19 related future research projects	Yes/No
I agree to my stored samples and information to be shared with collaborators for COVID-19 related research approved by the HREC	Yes/No
The QoVAX SET Pilot study team may contact me to invite me for longer-term follow up studies, or other research.	Yes/No
I give permission to be contacted if in rare occasions any unexpected incidental findings that may affect my health or my family's health are found	Yes/No

So we can link your consent to your vaccine dose, survey responses, saliva and blood samples, tests and other health information, please provide your medicare number if you have one?

— — — — — — — — — — —

So we can send you a copy of the participant information and your consent form please enter your email address: _____

Please provide your preferred contact phone number: _____

Name of Participant (please print) First name _____ Last name: _____

Signature _____ Date _____

Declaration by Study Researcher (if consent is given in presence of study 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 Researcher
(please print) _____

Signature _____ Date _____

Thank you for consenting to participate.

You will now be asked to complete the Pre-vaccination questionnaire.

If you wish to contact the QoVAX SET team at any time please email QoVAXSETProgram@health.qld.gov.au

Form for Withdrawal of Participation

Title	*QoVAX SET Program – Pilot Phase*
Coordinating Principal Investigator/ Principal Investigator	*Professor Janet Davies*
Location	*Metro North Vaccine Command Centre* *Cairns and Hinterland Hospital and Health Services Vaccine Command Centre* *Metro South Hospital and Health Services Vaccine Command Centre*

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my vaccination or any routine treatment, my relationship with those treating me or my relationship with any Queensland Health Hospital and Health Services.

So we can link withdrawl of your consent survey responses, saliva and blood samples, tests and any other health information, please provide your medicare number if you have one?

— — — — — — — — — — —

So we can send you a copy of the confirmation of your withdrawl of consent form please enter your email address: _____

Please provide your preferred contact phone number: _____

Name of Participant (please print) First name _____ Last name _____

Signature _____ Date _____

Optional:
I request that all my biological specimens (saliva, blood) collected and banked be deleted, destroyed or returned to me if it is still identifiable.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Researcher (If consent is withdrawn in person)

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 Senior Researcher (please print) _____

Signature _____ Date _____