Participant Information and Consent Form

The content of this participant information and consent form will be replicated on the QoVAX Safety and Efficacy Trial (SET) website.
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 Mixed Dose 1 and 2 Study
Adult providing own consent

Title	Queensland COVID-19 vaccine (QoVAX) Mixed Dose 1 and 2 Study
Coordinating Principal Investigator	Professor Janet Davies on behalf of the investigator team
Locations	Metro North Health Queensland Covid-19 Vaccination Medical Service Taskforce

Part 1 What does my participation involve?

1 Introduction

Some people in Queensland have had different types of COVID-19 vaccines for dose 1 and 2, instead of both doses of the same vaccine. The Queensland COVID-19 Vaccine Taskforce want to check that people having received mixed vaccine doses have good vaccine responses. This clinical review of people who have had received mixed COVID-19 vaccines is not research.

You can consent for your survey responses, samples and test results to be used in COVID-19 vaccine research, or to be only reviewed by the Queensland COVID-19 Vaccine Taskforce for clinical reasons.

Participation in the QoVAX SET Mixed Dose 1 and 2 (QoVAX-MD1&2) Research Study is voluntary.

For comparison, if you have had two doses of the same COVID-19 vaccine, you may also join this research study.

You will be asked to a complete a survey and give saliva and blood samples. We will look at your immune system response and investigate factors that influence your COVID-19 vaccine responses.

This Participant Information and electronic Consent Form tells you about this study and what is involved so you can decide whether you want to join or not.Please read this information carefully.

You can ask any questions about the QoVAX Mixed Dose 1 and 2 study or want to know more about by email QoVAXmd1&2@health.qld.gov.au or phone (07) 3647 1053.

2 What is the purpose of the QoVAX MD1&2 study?

This study will investigate the effects of receiving mixed COVID-19 vaccine doses on immune responses. We will look at the factors that affect levels of immune responses and compare these between people who have had the same vaccine and those who have received mixed COVID-19 vaccine doses.

The knowledge from this study about COVID-19 vaccine responses will:

1. Provide information about the different COVID-19 vaccines available to people in the community including those whose immune system may be affected by other conditions, and
2. Help inform decisions about delivering vaccine boosters for people in Queensland including those of us who identify as Aboriginal and/or Torres Strait and/or South Sea Islanders, or as being from culturally and linguistically diverse backgrounds.

3 What does participation in the QoVAX MD1&2 study involve?

You will be asked to complete a survey that takes about 10 minutes and give a saliva and some blood sample. We may invite you to give more samples one year after the COVID-19 vaccination dose one.

The samples will be tested for immune response and gene variants that may alter immune outcomes. Genetic array tests will include DNA sequencing of small parts of your genome. The purpose of these tests, and the survey questions, are to find factors that may be associated with people's vaccine response.

The survey will ask about:
1) your general health, background, wellbeing and lifestyle, and
2) your COVID-19 vaccine experiences, including any adverse reactions.

For privacy, your information will be stored securely with a unique study code. Samples collected will be de-identified for testing and storage. Survey responses, any adverse reaction reports, other health information (e.g. hospital records, COVID-19 test results), and results from this research, will all be linked securely in a QoVAX SET research biobank and databank.

Test results will be reviewed by the Queensland COVID-19 Vaccine Taskforce and used for health surveillance, or for further COVID-19 research depending on what you give consent for.

There is no cost to take part, and you will not be paid. We appreciate you going to a pathology collection centre to give samples. This research is based on looking at these samples so we can measure your immune system response four to six months after the COVID-19 vaccination dose two. You can chose to use a public or private pathology service.

4 What do I have to do?

Click the link and complete the survey on your smart phone, tablet or computer. You will then be sent **pathology request forms** by email, or mail if requested by you. Take the pathology request forms any Pathology Queensland collection centre, or nominated QML Pathology collection centre. These are the sample we need you to give at the collection centre:

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

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

5 Other relevant information about the research project

One of the health professionals of the Queensland COVID-19 Vaccine Taskforce may contact you if there are any concerns about your test results.

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

Participation is voluntary. If you don't want to be part of the study, then after your information and test results have been reviewed by nurses from the Queensland COVID-19 Vaccine Taskforce, your information will only be retained for health purposes, and not for research.

You can choose to withdraw from the QoVAX MD1&2 study at any time no questions asked by visiting the QoVAX SET website. Once we receive your request to withdraw from the study, your biological specimens will be destroyed or returned to you, and your information will no longer be available for research after that date.

7 What are the possible benefits of taking part?

You may benefit from this study because your individual response to the COVID-19 vaccine will be reviewed by one of the nurses in the QLDQueensland COVID-19 Vaccine Taskforce. When the nurse checks your test results, any concerns will be identified and managed. You will only be contacted by the nurse if you need any follow up care. You may be considered for booster vaccine doses at a later stage.

Through this research study, we aim to better understand how effective the different COVID-19 vaccine dose combinations are in the Queensland population. This will help planning for COVID-19 vaccination, for example regarding booster doses, and decisions around other public health measures in place to protect Queenslanders.

The research will also provide information about the benefits of the COVID-19 vaccine responses for different people in the community whose immune system may be weakened by health conditions or some types of medication.

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

There should 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 could affect your health or your families' health. If this is the case, then you will be contacted by nurse from the COVID-19 Vaccine Taskforce.

You may be required to disclose that information to third parties (for example, insurance companies or employers). If a serious finding is made it might have an effect on any insurance you apply for in the future (for example life insurance or income protection).

If you have concerns about this occurring, please discuss with one of our investigators prior to completing the consent form.

9 What will happen to my test samples?

If you choose to join the research study then, your biological samples (saliva and blood), survey and clinical data will be stored in the study biobank and linked databank for future use in COVID-19 related research projects including the investigation 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 test results indicate 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 be offered to you by one of the COVID-19 Vaccine Taskforce doctors.

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

Results of the research will combined, analysed and reported in academic articles and reports to COVID-19 vaccine decision-makers. We don't give individual results to participants because we don't yet know how immune responses measured for research relate to protection from the virus.

You will be able to see a summary of these results on the QoVAX SET website.

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

This research is not sponsored by any drug or biotechnology companies. We will not share raw data or samples collected for this QoVAX SET MD1&2 study with biotechnology companies without asking for 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 value and benefit from doing this QoVAX SET study, samples and data that have been collected and generated, will be made available to other eligible researchers for future COVID-19 research studies.

Any future COVID-19 research will be approved by a Human Research Ethics Committee (HREC), and the QoVAX Scientific Access Committee, and if relevant, the QoVAX Indigenous Steering Committee.

The research team will store your de-indentified samples, health and research data linked to them, securely in the QoVAX Queensland Digitally Integrated Biobank for COVID-19, managed by Pathology Queensland.

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

You and other people in the community might benefit if researchers learn more by using your samples to answer further research questions about COVID-19 vaccines.

Knowledge from this research may inform decisions by Queensland Health and Aboriginal and Torres Strait Islander Community Controlled Health Organisation on when to give people in our community vaccine booster doses.

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, and this will be your choice.

If we do need to contact you, we will use the contact details you have provided as part of the consent form and survey.
Combined research outcomes and new knowledge will be shared on the QoVAX public webpage.

16 QoVAX study databanking of Health Information

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 MD1&2 study, or for future COVID-19 related health research.

We will not use your personal health information for unrelated research without asking your consent.

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

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 databank for use in COVID-19 related research.

The QoVAX Indigenous Steering Group will review and make collective decisions about reporting of outcomes and stewardship of samples and data from Aboriginal and/or Torres Strait Islander and/or South Sea Islander people.

Part 2 How is the research project being conducted?

17 What will happen to information about me?

Only the primary chief investigators in QCVMS and the QoVAX SET Program will be able to access your personal details; the other investigators will use your unique study code. Your information will only be used for the purpose of this research project, and COVID-19 vaccine related-research projects approved by the QoVAX Scientifc Access Committee for this project and the Human Research Ethics Committee.

In any reports and presentations, information will be provided in 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 (QoVAXmd1&2@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 MD1&2 study or your participation please contact us at QoVAXmixed1&2@health.qld.gov.au

19 Who has reviewed the research project?

The QoVAX MD1&2 study has been reviewed by an independent group of people as part of the Royal Brisbane and Women's Hospital Consumer Advisory Group and the Human Research Ethics Committee.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)- Updated 2018* and AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (2020). These statements have been developed to protect the interests of all 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	Director QoVAX SET Program
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	MNHHS Research Governance Manager
Telephone	07 3647 9550
Email	MNHHS-RGO@health.qld.gov.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:

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 Mixed Dose 1 and 2 Study Investigator team

Prof. Janet Davies	Director, QOVAX SET Safety and Efficacy Program, Metro North Health, Head of Allergy Research, Centre Immunology and Infection Control, Queensland University of Technology	Principal Coordinating Investigator
Dr Bav Manoharan	Clinical Lead, Queensland Covid-19 Vaccination Taskforce	Investigator
Dr Andrew Redmond	Infectious Diseases Physician, Royal Brisbane and Women's Hospital	Investigator
Dr Peter Bourke	Cairns Hinterland Hospital and Health Service	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 Hannah Carter	Research Fellow Health Economics, Australian Centre for Health Services Innovation, Queensland University of Technology	Investigator
Assoc. Prof Emma Ballard	Senior Biostatistician	Investigator
Ms Kirsty Leo	Manager, Data, Research and Clinical Governance, Aboriginal & Torres Strait Islander Leadership Team, Metro North Health	Associate Investigator
Mr Greg Pratt	Manager of the Aboriginal & Torres Strait Islander Health	Associate Investigator
Stephanie Gras	Professor Stephanie Gras, Viral and Structural Immunology laboratory Head, NHMRC Senior Research Fellow, La Trobe Institute For Molecular Science, La Trobe University	Associate Investigator
Dr Nic Waddell	Coordinator of the Cancer Program, Head of Medical Genomics Laboratory, QIMR Berghofer	Associate Investigator
Dr David Gillis	State Director – Immunology, Pathology Queensland	Associate Investigator
Rebecca Gregory	Scientific Program Lead – QoVAX SET, Metro North Health	Associate Investigator

Consent Form

Title	*QoVAX SET Mixed Dose 1 & 2*
Coordinating Principal Investigator	*Professor Janet Davies*
Locations	Metro North Health Queensland Covid-19 Vaccination Taskforce

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, risks and benefits for this research. 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 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 de-identified samples and information to be shared with collaborators for future COVID-19 related research that is approved by the HREC, and the QoVAX Scientific Access Committee, AND if relevant, the QoVAX Indigenous Steering Committee.	Yes/No
The QoVAX SET team may contact me to invite me for follow up studies, or other research.	Yes/No

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

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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 _____

Thank you for consenting to participate.

You will now be asked to complete the questionnaire.

If you have any questions about this study, please contact us here:
If you wish to contact the QoVAX SET team please email
QoVAXmd1&2@health.qld.gov.au

or phone (07) 3647 1053 and ask about the QoVAX Mixed Dose 1 and 2 study.

Form for Withdrawal of Participation

Title	*QoVAX SET Mixed Dose 1 & 2*
Coordinating Principal Investigator/ Principal Investigator	*Professor Janet Davies*
Location	Metro North Health Queensland Covid-19 Vaccination Taskforce

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?

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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(s) _____ 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 _____