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Participant Information and Consent Form (Group A)

Title: PRospEctiVe EvaluatioN of immuniTy after COVID-19 vaccines (PREVENT-COVID)

Co-Principal Investigators:

- Dr. Manish Sadarangani, BM BCh DPhil *(Vaccine Evaluation Center [VEC], BC Children's Research Institute [BCCHRI] and University of British Columbia [UBC])*
- Dr. Agatha Jassem, PhD FCCM *(Public Health Laboratory [PHL], BC Centre for Disease Control [BCCDC] and UBC)*
- Dr. Muhammad Morshed, PhD SCCM *(PHL, BCCDC and UBC)*
- Dr. Inna Sekirov, MD PhD *(PHL, BCCDC and UBC)*

Study Co-Investigators:

- Dr. Sofia Bartlett, PhD *(PHL, BCCDC and UBC)*
- Dr. Mel Krajden, MD *(PHL, BCCDC and UBC)*
- Dr. Megan Levings *(BCCHRI and UBC)*
- Dr. Danuta Skowronski, MD *(BCCDC and UBC)*
- Dr. Theodore Steiner, MD *(BCCHRI and UBC)*
- Dr. James Zlosnik, PhD *(VEC, BCCHRI and UBC)*

Sponsor: University of British Columbia
Funder: University of British Columbia

Emergency Telephone Number: 604.220.5572 (24 hours, 7 days a week)
Non-Emergency Telephone Number: 604.875.2422

If you are a substitute decision-maker (legally authorized representative) for someone who may take part in this study, permission from you and the assent (agreement) of the potential research participant may be required. When we say "you" or "your" in this consent form, we mean the research participant; "we" means the doctors and other research staff.

INVITATION

You are being invited to take part in this study because we are researching the immune response to COVID-19 vaccines.

If your substitute decision maker consents to your participation on this study on your behalf, we will ask you to confirm your continued willingness to participate in the study once you've re-gained ability to consent for yourself.

YOUR PARTICIPATION IS VOLUNTARY

Your participation in this study is completely **voluntary**. If you decide not to participate, you do not have to give a reason. If you choose to take part in the study, you will be asked to sign an online consent form. If you decide to take part in the study now and later change your mind, you are free to withdraw at any time without any consequences.

WHO IS CONDUCTING THE STUDY?

This study is being done by doctors and research staff in BC who specialize in vaccines and infections at the Vaccine Evaluation Center (VEC) at the BC Children's Hospital Research Institute (BCCHRI) and the Public Health Laboratory (PHL) at the BC Centre for Disease Control (BCCDC) in Vancouver. The Principal Investigators are Dr. Manish Sadarangani from the VEC, and Drs. Agatha Jassem, Muhammad Morshed and Inna Sekirov from the BCCDC PHL. The money to do this study has been provided through the University of British Columbia. The Investigators will not receive personal payments for doing this study. There will be up to 5,000 adults per COVID-19 vaccine in BC enrolled in this study.

WHAT IS THE BACKGROUND OF THE STUDY?

SARS-CoV-2, the virus responsible for COVID-19, has infected millions of people worldwide since its emergence in late 2019. Multiple COVID-19 vaccines will be used in Canada and best use of these vaccines will help us control the pandemic as quickly as possible. Most vaccine companies have used their own tests to measure immune responses to their vaccines. Each vaccine company uses a different test and it is not possible to compare these results directly between different vaccine trials. Therefore, we do not know how the vaccines compare against each other – or how long immunity lasts after vaccination. Such comparisons are important to help us to use the different vaccines in the best possible way and also to directly compare the vaccines.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to measure the short- and long-term immune responses generated by different COVID-19 vaccines in adults, including those who were previously infected with SARS-CoV-2 or other coronaviruses. We will characterize the immunity generated by different COVID-19 vaccines. We will explore the influence of previous infection with human coronaviruses, including SARS-CoV-2 and other coronaviruses, on the response to COVID-19 vaccines.

WHO CAN PARTICIPATE IN THIS STUDY?

To be included in the study, you have to be willing to sign the consent form, or there is a substitute decision maker to provide informed consent if you are unable to at this time, and you will need to meet all of the following inclusion criteria:

- You are an adult aged at least 19 years of age at time of the study
- You are due to receive a COVID-19 vaccine as part of your standard care (we will not be providing COVID-19 vaccines as part of this study)

WHO SHOULD NOT PARTICIPATE IN THIS STUDY?

You will not be eligible to participate in this study or if you are unwilling to sign the consent form.

WHAT DOES THE STUDY INVOLVE?

If you agree to take part in this study, you will have a total of up to 9 virtual study visits (which can be done from your home) over a period of 18 months. This will take a total of approximately 90 minutes of your time.

The first study visit will be ideally be the same day or up to 24 hours before you receive the first dose of your COVID-19 vaccine.

At the first study visit, you will be asked to complete an initial questionnaire, which will take less than 5 minutes. You will be asked questions regarding your background (for example, age, sex, and race), your medical history, and which COVID-19 vaccine you are receiving.

We will provide you a kit with instructions and materials you will need to collect a blood sample at home, which will take approximately 10 minutes to do. The kit includes lancets that you will use to do a finger prick, and a 5-spot specimen card to collect a few drops of blood onto. You will be asked to clean the tip of the middle or ring finger of your non-dominant hand, gently prick your finger using the provided lancet, and touch the card so drops of blood can soak through and fill each of the 5 circles on the specimen card. You will also be provided detailed instructions with pictures on how to do the blood collection and mail the sample back to us at no cost to you. You may ask someone to help you with this, and in some circumstances a study nurse or research assistant may also be available to help.

The second study visit will be ideally be the same day or up to 24 hours before you receive the second dose of your COVID-19 vaccine. If you are only receiving a single dose of COVID-19 vaccine, this visit will not be needed. You will be asked if there have been any changes to your medical history and be asked to collect another blood sample using a finger prick (as above) and mail the sample back to us at no cost to you. If you do not receive a second dose of COVID-19 vaccine, you will not have to do this visit. If there is a long gap (more than approximately 6 weeks) between your 2 doses of vaccine, you may have to have 2 separate samples collected instead of one – the first sample 3-6 weeks after the first dose and the second sample at the time of your second dose.

The remaining six study visits (visits 3 to 8) will occur 1, 3, 6, 9, 12 and 18 months after your last dose of COVID-19 vaccine. These will be the same as your second study visit. You will be asked if there have been any changes to your medical history (via an online survey as in the previous study visits) and be asked to collect another blood sample using a finger prick and mail the sample back to us at no cost to you.

The PI and/or their delegate may also review or complement study information collected with any COVID-19 tests you have had from within public health and laboratory diagnostic records as necessary to aid in the interpretation of findings. We will ask you for your Personal Health Number to do this, but this information will be kept strictly confidential – see section 'HOW WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?'

WHAT ARE THE POSSIBLE HARMS OR DISCOMFORTS?

Collecting a finger prick blood test may cause some mild discomfort or pain but should be temporary. The collection only requires a minimal amount of blood (less than 0.5 mL), and the risk of a local infection from the finger poke is very small (less than 1%). There are no expected harms or discomforts associated with participating in the questionnaire. There may be a risk of loss of confidentiality, but this consent form will tell you in the later sections all the steps that will be taken to minimize the chance of this happening.

WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?

There is unlikely to be any direct benefit to you for taking part in this study. We do not yet fully know how the tests we do in the lab relate to protection against COVID-19, so we will be unable to tell from your study results whether you are fully protected against COVID-19. Results from this study may provide researchers and policy makers information about how to best use

COVID-19 vaccines in the future. This may improve your own care in the future, if you need to receive COVID-19 vaccines again.

Research conducted using the data that you have contributed may lead to the creation of new diagnostic tests, drugs, treatments, methods, or other products that are commercial or proprietary. If this occurs, you will not be notified, and you will not receive any share of the profits derived from the sale, use, or commercial exploitation thereof.

WHAT ARE THE ALTERNATIVES TO STUDY TREATMENT?

There are no treatments involved in this study, and thus no alternatives to study treatment. If you choose not to participate, you can still receive your COVID-19 vaccine as normal.

WHAT WILL HAPPEN TO MY SAMPLES?

Your samples will be analyzed in the laboratories at the VEC, BCCHRI or BCCDC where tests will be done to measure the immune response generated from the COVID-19 vaccine. All samples will ultimately be transferred to BCCDC.

There is a possibility that researchers may need to collect additional samples to further their research in COVID-19. In that case, research staff may approach you and explain what will be involved, and no additional samples will be collected until you provide your permission and sign a separate consent form. All study related samples will be coded (this means it will not contain your name or personal identifying information) before leaving the study site.

WHAT WILL HAPPEN AFTER THE STUDY IS FINISHED?

All study related documents will be maintained at the VEC, BCCDC, or in an off-site secure storage location for a total of 10 years, after which the documents will be destroyed. Information about the results of this study will be emailed/mailed to you once the study is over and the results have been generated.

Samples will be retained for up to 10 years at the BCCDC for the purposes of the study and/or for further investigating SARS-CoV-2, other coronavirus and/or other emerging or re-emerging respiratory virus immune responses, after which they will be destroyed. De-identified specimens and data may be shared with national and/or international partners deemed necessary and appropriate by the BCCDC under data and specimen sharing agreements for research purposes mentioned above. The decision to share specimens or data will be made by the study investigators, and in line with the uses stated here. None of the shared specimens will contain information that could identify you personally. No human genetic testing will be done on human DNA that may be present in the samples.

WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT MAY AFFECT MY DECISION TO PARTICIPATE?

Since this study does not involve a treatment protocol, it is unlikely that new information will become available that could potentially affect your willingness to remain in the study. If changes do occur in the future, you may be asked to sign an amended consent form to indicate your continued consent to participate.

WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, the study team will have a discussion with you about what will happen to the information about you and your samples already collected. You have the right to request the destruction of your information and/or samples collected during the

study, or you may choose to leave the study and allow the investigators to keep the information already collected about you until that point.

If you choose to have the data collected about you destroyed, this request will be respected to the extent possible. Please note however that there may be exceptions where the data and/or samples will not be able to be withdrawn for example where the data and/or sample is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data or samples, please let your study doctor know.

CAN I BE ASKED TO LEAVE THE STUDY?

You may be asked to leave the study if the study doctor judges it is not in your best interest to continue, if you are unable to fulfill the requirements for the study, or for any other reason. If you are asked to leave the study, the reasons for this will be explained to you and you will have the opportunity to ask questions about this decision.

HOW WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

The research staff at the VEC and BCCDC respect your confidentiality, and will keep all personal information collected about you confidential, unless required by law. However, research records may be inspected by designated representatives of the study sponsor or the UBC/C&W Research Ethics Board for the purpose of monitoring research. No information or records that disclose your identity will be published without your consent, and any records which identify you will not be removed or released from the study office without your consent, unless required by law. A unique code number will be assigned to you and any research data collected about you during the study will not identify you by name, only by your unique code number. This will keep your information confidential, and the list that attaches your name to your code number will not be removed or released without your consent. Therefore, this information is de-identified and cannot be withdrawn at a later date.

You will be given a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include name, Personal Health Number, Social Insurance Number, or initials). The number will be used on any research related information that goes outside the study site so that only VEC/BCCDC doctors and study staff will know your personal information. There will be a list that matches your name to the unique study number that is used on research-related information. Neither your personal information nor this list will be removed from the VEC/BCCDC, released or written into reports without your consent unless required by law. However, research records, personal and health information or other source records identifying you may be looked at in the presence of the Investigator or his designate by representatives from the ethics committee at UBC, BC's Children's and Women's Hospitals, to make sure that the study is being done properly. They can only see your personal information with the study doctors or staff nearby and cannot take anything away from the study site.

The data we collect from you will be entered into "REDCap", a secure online database that is designed for collecting, managing and reporting clinic research data. When your data is entered into REDCap, it is immediately encrypted during transmission and can only be accessed by username and password.

Your rights to privacy are legally protected and will always be respected. You also have the legal right to access any of the information that we collect about you and you will be given an opportunity to correct any errors in this information. You can always ask for more details about these laws if you want to know more details. While every effort will be made to protect the privacy

of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of researchers and others to protect your privacy.

YOU CAN EXPECT THAT

1. Information collected will be kept private and only used for this study.
2. Unless required by law, no personal information will be given to anyone outside this study centre.
3. Your name or information that identifies you will not be in any publications or reports.

Future researchers may ask for data from this study to help with their research into COVID-19. Any such requests would be reviewed by the study team. If data are shared, it would be de-identified data and no personal information will be shared.

WHAT HAPPENS IF SOMETHING GOES WRONG?

Signing this consent form does not limit your legal rights and you do not release the study doctor, participating institutions, or anyone else from their legal and professional duties.

WHAT WILL THE STUDY COST ME?

There is no cost for taking part in this study and you will not be paid or reimbursed for taking part.

IF I HAVE QUESTIONS DURING MY PARTICIPATION, WHO SHOULD I SPEAK TO?

If you have any questions, would like further information, or if you experience any adverse events throughout the duration of the study, you can contact the Principal Investigator (Dr. Manish Sadarangani) or the Study Coordinator at 604.875.2422. After-hours emergency: 604.220.5572.

WHO DO I CONTACT IF I HAVE CONCERNS ABOUT MY RIGHTS AS A PARTICIPANT?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604.822.8598 (Toll Free: 1.877.822.8598). Please reference the study number (H20-03951) when contacting the Complaint Line so the staff can better assist you.

FUTURE STUDIES

If you are willing to hear about future studies, please mark "yes" on the e-consent online survey. The VEC will keep your personal information (name, contact information, date of birth etc.) on a secure database indefinitely for the purpose of contacting you with information about upcoming studies we are conducting. This does not mean that you will have to take part in a new study, just that we will let you know about it. If you do not want to hear about new studies, please mark "no".

YES □ **NO** □ Participant Initials_____

If are joining this study using paper consent, please continue to the signature page below.

If you are joining this study remotely, or by electronic device, you will be sent a link to sign an E-Consent Signature page online.

ELECTRONIC CONSENTING FOR REMOTE PARTICIPANTS

If you wish to participate in this study, you will be sent a link to sign an Electronic Consent (e-consent) Signature page online. Your e-consent form will be stored in the BC Children's Hospital Research Institute's secure network in Vancouver, BC. Only authorized personnel will be able to access it.

A copy of your e-consent form will be automatically sent to your email address for you to keep for your records. However, please note that some webmail services (e.g. Gmail, Hotmail, etc.) may store/route emails outside of Canada. Due to the fact that future emails may contain personal information about you, including your name, the Freedom of Information and Protection of Privacy Act requires that we obtain your consent before we continue.

Signing this e-consent will mean that you:

- Have read and understood the information in this consent form
- Have had enough time to think about the information
- Have been able to ask questions and have had satisfactory responses
- Understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes
- Understand that participation in this study is voluntary and that you are completely free at any time to refuse to participate or to withdraw from this study and that this will not change the quality of care you receive
- Give permission to use and share your health data and bio-specimens as described in this form
- Give permission to have your email address used to send personal information, as per the Freedom of Information and Protection of Privacy act
- Understand that you are not waiving any of your legal rights as a result of signing this consent form
- Understand that there are no direct benefits to you from participating in this study
- Voluntarily consent to participate in this research study.

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UBC

Participant Information and Consent Form (Group A)

Title: PRospEctiVe EvaluatioN of immuniTy after COVID-19 vaccines (PREVENT-COVID)

My signature on this consent form means:

- I have read and understood the information in this Consent Form (all 6 pages)
- I have had enough time to think about the information, and have been able to ask for advice if needed
- I have been able to ask questions and have had satisfactory responses to my questions
- I understand that all of the personal information collected will be kept confidential and that the results will only be used for scientific purposes
- I understand that my participation in this study is voluntary and that I am free to withdraw from the research study at any time without explaining my decision to do so and without it affecting my medical care
- I may have to leave the study without my consent if I need other treatment, do not follow the study plan or for any other reason
- I give permission to use and share my health data as described in this form
- I understand that I am not waiving any of my legal rights as a result of signing this consent form
- I understand that there is no guarantee that this study will provide any benefits to me
- I will receive a signed dated copy of this consent form for my own records
- I voluntarily consent to take part in this research study

Participant's full name: _____

Signature: _____

Date: Day _____ Month _____Year _____ Time: _____am/pm

I certify that I have explained the nature and purpose of this research study, and the potential benefits and reasonably foreseeable risks associated with participation, to the above volunteer, on the date stated on this consent form. I have answered any questions that were raised and have witnessed the above signature.

Name of study staff: _____ **Signature**: _____

Date: Day _____ Month _____Year_____

Participant Information and Consent Form (Group A)

Title: PRospEctiVe EvaluatioN of immuniTy after COVID-19 vaccines (PREVENT-COVID)

By signing below, I agree that this consent form was read by the substitute decision-maker (legally authorized representative), and both the person reading this consent form and the investigator are satisfied that:

- The study information was accurately explained to me, and apparently understood by the participant
- I and the participant have had enough time to think about the information, and have been able to ask for advice if needed
- I and the participant have been able to ask questions and have had satisfactory responses to my questions
- I understand that all of the personal information collected will be kept confidential and that the results will only be used for scientific purposes
- I understand that my participation in this study is voluntary and that the participant is free to withdraw from the research study at any time without explaining the decision to do so and without it affecting the participant's medical care
- The participant may have to leave the study without consent if he/she needs other treatment, does not follow the study plan or for any other reason
- I give permission to use and share the participant's health data as described in this form
- I understand that I am not waiving any of my or the participant's legal rights as a result of signing this consent form
- I understand that there is no guarantee that this study will provide any benefits to the participant
- I will receive a signed dated copy of this consent form for my own records
- The participant assents to participating in the research

Participant's full name: _____

Substitute decision maker's full name: _____

Signature: _____

Date: Day _____ Month _____Year _____ Time: _____am/pm

I certify that I have explained the nature and purpose of this research study, and the potential benefits and reasonably foreseeable risks associated with participation, to the above volunteer, on the date stated on this consent form. I have answered any questions that were raised and have witnessed the above signature.

Name of study staff: _____ **Signature**: _____

Date: Day _____ Month _____Year_____

Participant Information and Consent Form (Group A)

Title: PRospEctiVe EvaluatioN of immuniTy after COVID-19 vaccines (PREVENT-COVID)

Was the participant assisted during the consent process?

☐ Yes ☐ No

If yes, please check the relevant box and complete the signature space below:

☐ The consent form was read to the participant, and the person signing below attests that the study was accurately explained to, and apparently understood by, the participant (please check if participant is unable to read).

_____	_____	_____
Signature of Person Assisting	*Printed Name*	*Date*

Participant Information and Consent Form (Group A)

Title: PRospEctiVe EvaluatioN of immuniTy after COVID-19 vaccines (PREVENT-COVID)

Participant's Acceptance of Substitute Decision Maker's Consent:
It was impossible for you to participate in the informed consent process at the time of study enrolment, so your substitute decision maker's (SDM) consent was obtained on your behalf. Your SDM agreed to your participation in this research study. Now that you are able to consent for yourself we would like to inform you of the details of the study and obtain your consent. The Participant Informed Consent Form will be reviewed with you and then you may agree or disagree with the decision made by your SDM.

If you do not wish to continue participation in this study you may request that your study data be withdrawn. This request will be respected to the extent possible. Please note however that there may be exceptions where the data or samples collected from you will not be able to be withdrawn. You may discuss this further with the study doctor.

My signature on this consent form means:

- I have read and understood the information in this Consent Form (all 6 pages)
- I have had enough time to think about the information, and have been able to ask for advice if needed
- I have been able to ask questions and have had satisfactory responses to my questions
- I understand that all of the personal information collected will be kept confidential and that the results will only be used for scientific purposes
- I understand that my participation in this study is voluntary and that I am free to withdraw from the research study at any time without explaining my decision to do so and without it affecting my medical care
- I may have to leave the study without my consent if I need other treatment, do not follow the study plan or for any other reason
- I give permission to use and share my health data as described in this form
- I understand that I am not waiving any of my legal rights as a result of signing this consent form
- I understand that there is no guarantee that this study will provide any benefits to me
- I will receive a signed dated copy of this consent form for my own records
- I voluntarily consent to take part in this research study

Participant's full name: _____

Signature: _____

Date: Day _____ Month _____Year _____ Time: _____am/pm

I certify that I have explained the nature and purpose of this research study, and the potential benefits and reasonably foreseeable risks associated with participation, to the above volunteer, on the date stated on this consent form. I have answered any questions that were raised and have witnessed the above signature.

Name of study staff: _____ **Signature**: _____

Date: Day _____ Month _____Year_____