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(REMOTE) PARTICIPANT INFORMATION AND CONSENT FORM

Title: The SPRING Study: Severe acute respiratory-syndrome related coronavirus 2 prevalence in children and young adults in British Columbia: an observational study

Principal Investigator:
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Co-Investigators:

- Dr. Bahaa Abu Raya MD (VEC, BCCHRI & UBC)
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Emergency Telephone Number: 604.220.5572 (24 hours, 7 days a week)
Non-Emergency Telephone Number: 604.875.2422

INVITATION

You are being invited to take part in this research study because we are researching how the COVID-19 pandemic has affected children and young adults under 25 years of age.

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?

The study is being conducted by doctors in BC who specialize in infectious diseases. The Principal Investigator is Dr. Manish Sadarangani. The study is being run in through the Vaccine Evaluation Center

at the BC Children's Hospital Research Institute. This study was reviewed and approved by the UBC/C&W Research Ethics Boards. The money to do this study has been provided through the Michael Smith Foundation for Health Research and the Public Health Agency of Canada. The Investigators will not receive personal payment for leading this study. There will be up to 16,000 children and young adults (under 25 years of age) in BC enrolled in this study.

WHAT IS THE BACKGROUND OF THE STUDY?

Many COVID-19 cases in children, as well as in adults, have been with mild or no symptoms. Doctors believe that people who have no symptoms can still transmit the virus to others. This asymptomatic transmission creates a significant public health concern, since people with no symptoms may expose a far greater number of people to the virus than those who have symptoms and are isolating or taking precautions. This makes it harder to control outbreaks and makes it difficult to make decisions around when to open schools, day-cares, and other public spaces.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to collect information from individuals who are under 25 years of age living in BC, to help us understand the rates of COVID-19 infection, even amongst those who may have had no symptoms, and the impact of COVID-19 vaccination. The researchers will combine the information they get from this study with that of similar studies across BC, in order to help doctors better understand the spread of the virus and better understand how to safely allow people back to schools, day-cares, and other public places.

WHO CAN PARTICIPATE IN THIS STUDY?

To be included in the study, you have to be willing to sign the consent form and you will need to meet all of the following inclusion criteria:

1. Under 25 years of age at the time of the study
2. Resident of British Columbia at the time of the 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?

Please go through the information in this consent form and ask the research staff any questions you might have. You will receive a copy of the consent form for your records. Once signed, you will be granting permission for the transfer of information collected through your virtual visit.

Taking part in the study will involve completing a questionnaire, which will take 10-15 minutes. You will be asked questions regarding your background (for example, age, sex, and race), your general health and lifestyle, your medical history, any symptoms that might be related to COVID-19, COVID-19 vaccination history, and your opinions on vaccines.

Then, we will mail 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.

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 or telephone follow up calls. 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. Since COVID-19 is a reportable disease, if you do have a positive result, you may be contacted by a Medical Health Officer to follow up, and potentially have more testing.

WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?

You will be notified of your blood test results, which will show whether or not you have developed antibodies against the COVID-19 virus. The information collected from you will also help improve the Canadian response to COVID-19 and other future outbreaks. This may improve your own care in the future.

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 get tested for COVID-19 through public health according to the provincial rules.

WHAT WILL HAPPEN TO MY SAMPLES?

Your samples will be analyzed in the laboratory at the VEC, BC Children's Hospital or BC Centre for Disease Control (BCCDC) where tests will be done to determine whether you have antibodies against the COVID-19 virus (indicating past COVID-19 infection or the result of COVID-19 vaccination). All samples will then 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. Once the study has been completed, if any sample is left over, it will be destroyed.

The tests being used in this study have been validated for research use only. While we will inform you if the tests are positive or negative, these are not a replacement for medical diagnostic tests for COVID-19. If at any time during this study you are recommended by a healthcare provider to have a test for COVID-19 or if you need a COVID-19 test for any other reason, you should still go ahead and have that test at a standard testing clinic. As well, if your antibody test is positive for COVID-19, that does not necessarily mean you are 'immune' or protected against future infections. You should continue to follow all public health guidance.

WHAT WILL HAPPEN AFTER THE STUDY IS FINISHED?

All study related documents will be maintained at the VEC, or in an off-site secure storage location for up to 25 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 25 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. 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, and without consequence. If you choose to enter the study and then decide to withdraw at a later time, all information about you collected up to the point of the withdrawal will be retained for analysis in order to protect the integrity of the research. However, no further information will be collected.

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 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 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, 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 (H20-01886) 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'S INITIALS** _____

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.