TRACKING COVID TO HELP MAKE OUR SCHOOLS SAFER

PARTICIPANT INFORMATION AND CONSENT FORM

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Study Sponsor: Public Health Agency of Canada

STUDY PURPOSE

You are being invited to participate in this study because you are a school staff member. The main purpose is to understand to what extent educator and support staff working in schools have been exposed to COVID-19. We hope that this study will inform strategies to mitigate the risk of COVID-19 exposure in the school setting. This study will enroll up to 2,900 school staff members, comparing between classroom educators who work in direct contact with students versus school administrators/support staff who are not working directly with students.

YOUR PARTICIPATION IS VOLUNTARY

Your participation is voluntary. If you decide to participate, you may still choose to withdraw from the study at any time. This consent form describes the procedures that are being carried out for research purposes. Please review the consent document carefully when deciding whether or not you wish to take part in this research. If you wish to participate in this study, you will be asked to sign this form. Please take time to read the following information carefully and to discuss it with your colleagues, family, or friends before you decide. If you have any questions about this study, feel free to email Lauren at abcovid@bcchr.ca, indicating how she can get back to you within 24h (email or phone contact).

WHO IS CONDUCTING THE STUDY?

This study is funded by the Public Health Agency of Canada and is conducted by researchers at the University of British Columbia and the BC Children's Hospital Research Institute in Vancouver. The main

investigators are Pascal Lavoie and Louise Mâsse. None of the investigators receive direct compensation to conduct this study.

WHO CAN PARTICIPATE IN THIS STUDY?

If you are a staff member within the Vancouver, Delta or Richmond School Districts you can participate in this study. As part of this study, we will be enrolling about 2,400 educators who work in direct contact with students, and about 500 school staff who are not in direct contact with students.

WHO SHOULD NOT PARTICIPATE IN THIS STUDY?

If you think you may have been exposed to COVID-19 in the past 14 days, you currently have COVID-19 you should quarantine yourself according to public health directives. You can still participate once you are no longer contagious. This study involves two blood tests. If you are uncomfortable with blood collection, please email the study coordinator to find out about skipping this part of the study.

STUDY INVOLVEMENT

If you decide to join this study, you will be asked to provide some contact information and participate in two data collection periods which will take place in:

1) January to April 2021
2) June or July 2021

At each data collection time point, you will complete some questionnaires and have a blood test.

The contact information form will collect: your *name*, *date of birth*, your *phone number* and your *school district email address*. Your name and email address are needed to send you information to complete all of the components of the research study, and to send you your blood results and incentive for participation by email. A phone number will help us contact you if you can't be contacted by email. This information will be stored in a separate file from your blood results or responses to the questionnaires. A school district email address is used to verify your eligibly for this study as a current district employee, however, no information about your participation in this study, questionnaire responses or blood results will be shared with your school or school district.

The questionnaires consist of 1) a general questionnaire including demographic information (e.g. your age, sex, gender, ethnicity, education and *first 3 digits of your postal code, etc.)*. The first three digits of your postal code will be used to geographically map exposure to COVID-19. It indicates your neighborhood area, but not your exact address. The questionnaires will also ask whether you had COVID-19 in the past, general health condition, social distancing practices, lifestyle, living conditions and travel; the impact COVID-19 or its mitigation measures may have on your psychological health; and your level of interest in receiving a vaccine against COVID-19 (the latter is about your perception of the vaccine, and is not a consent to receive the vaccine). Completing these questionnaires should take you between 20 to 30 minutes, and can be completed as your time permits, over a week.

Getting a blood test: After completion of the questionnaire, you will be given the opportunity to book an appointment at a blood collection clinic that is at a convenient time and location for you (example of possible locations: select secondary schools, Life Labs, BC Children's Hospital or St. Paul's Hospital). You will be provided instructions on how to book your appointment using an online booking system (such as JANE app for in-school blood clinics or other online booking systems for Life Labs and St. Paul's Hospital). You will be emailed a blood requisition to take with you to the testing location to

have a serology test (6 mL, or less than a teaspoon or blood will be collected). This blood requisition will include your name and date of birth.

Your blood will be tested for SARS-CoV-2 antibodies (serology testing): Blood samples will be tested at the BC Children's & Women's Health Centre. Your serology test results will not be shared or stored at Life Labs. Antibodies against SARS-CoV-2 measures whether someone has been infected with the virus in the past. It does not mean that a person has COVID-19 or can transmit the virus. A positive antibody test is not diagnostic for COVID-19 and does not require public health action, but is useful in a research setting to tell if someone has been exposed to the virus in the past. We will also analyze antibodies against other respiratory viruses, which will help us determine if your antibodies are specific to the virus causing COVID-19. Depending on Public Health guidelines the research team may host blood drives at convenient locations to provide an alternative place for participants to get their blood test taken.

Your serology result will be returned to you once it is available, using the email address you provided. A link to your test results will be sent by email, but to retrieve your results, you will have to enter an access code provided to you in a separate email. Your email will also be used to contact you for the follow-up questionnaires and blood collection in June/July 2021, and following that, every 3 months until March 2022 to find out if you were to develop COVID-19 in the future.

Further testing for those who have SARS-CoV-2 antibodies: If your blood test shows that you have been exposed to SARS-CoV-2 (i.e. is positive), we will invite you to come back within 2-4 weeks for more blood testing at BC Children's Hospital. These additional tests will require another 40 mL of blood (or three tablespoons) and will look at the immune response to the COVID-19 virus. At this visit, we will also collect a sample of saliva from you to measure antibodies there too. These tests will help determine how your body has responded to the virus. We hope that these extra tests will help understand how the body responds to COVID-19 and whether SARS-CoV-2-specific antibodies may protect against future infections. You may decide later that you do not want to do these extra tests, and this will not impact your participation in the rest of the study.

These additional serology tests will be carried out at the BC Children's Hospital's research institute and the National Institutes of Health in the US (in Bethesda, Maryland USA), as they have advanced analytical skills in this area. Your personal information WILL NOT be shared with the labs in the US. Your blood samples will only be used for the purpose of finding out about immune responses to COVID-19. All left-over blood will be destroyed after the study following established regulations for biomedical research.

De-identified/coded data related to you, but that can't identify you directly will be made available to the Canadian Immune Task Force (CITF) for the purpose of comparing with other COVID-19 studies. This includes serology and immune testing results, or data obtained through the questionnaires. The CITF will also receive the first three digits of your postal code to map community immunity to COVID-19. CITF is a national initiative funded by the Government of Canada to perform research related to COVID-19. The CITF will collect data to share with researchers in Canada and internationally to understand the science underlying COVID-19 immunity, COVID-19 infection rates in the Canadian population, and to study related health outcomes. The CITF studies will be performed in compliance with the CITF Principles. These are twelve guiding principles that are intended to ensure the effective, equitable, and transparent conduct of research. The CITF Principles can be consulted on the CITF website:

https://www.covid19immunitytaskforce.ca/principles/

At the end of this consent form, we will also ask if you are willing to be contacted by a research staff in the future to provide additional consent to make your blood sample available for other types of research. However, this is optional and is not part of this current study.

HOW AND HOW LONG WILL MY DATA BE STORED?

The data provided to the CITF will be stored on the CITF Database. The data on the CITF Database will be held under the custodianship of McGill University or one of its collaborators and be shared via the cloud, both nationally and internationally. The data on the CITF Database will be stored indefinitely, or until it is no longer useful for research, or the ethic's committee of the custodian University decides otherwise

BENEFITS OR POSSIBLE HARMS OF PARTICIPATING IN THIS STUDY

RISKS: Your data will be protected using current security safeguards. However, there remains a minimal risk that the security of your data could be compromised. This could happen if there is a malicious or inadvertent breach of security measures.

The risks involved in drawing blood from a vein may include, but are not limited to, feeling of lightheadedness when the blood is drawn, discomfort at the site of the blood draw, possible bruising, redness and swelling around the site, bleeding at the site, and rarely, an infection at the site of the blood draw. While there are no reported harmful effects of filling in the questionnaires, bringing up the subject of anxiety in questionnaires has the potential to cause emotional distress. If any of the questions in the forms cause discomfort, you can contact your family doctor or access the resources that are provided at the end of questionnaire. If you don't know where to get help, please contact the study coordinator (whose name appears at the top of this form) and we will do our best to help you obtain appropriate support.

BENEFITS: There will be no immediate benefits to you from participating in this study. However, the knowledge gained from our study will benefit the school community, guiding interventions to minimize stress and exposure from COVID-19. We are committed to sharing your serology result with you as soon as we are able to (hopefully within 2-4 weeks unless we encounter a delay with our study analyses). We will also share any other result that may come up from the more detailed immunology testing if you request it (note that these tests are purely research tests and do not provide information about the health of your immune system). A positive serology tests means that you have been infected with the SARS-CoV-2 virus in the past. It does not mean that you have *active* COVID-19 disease as the serology test will remain positive months after a COVID-19 infection even if you are no longer infectious. It is also important to clarify here that the current state of scientific knowledge does not allow us to predict whether positive antibodies confer any protection against COVID-19 for yourself or your ability to transmit the virus. Therefore, you should continue to follow <u>all public health guidance including vaccination recommendations</u>.

WHAT HAPPENS IF I LATER DECIDE TO WITHDRAW FROM THE STUDY?

Your participation is entirely voluntary. You may withdraw from this study at any time. If you decide to do so, data and samples that have already been collected will be analyzed unless you request that your

data be removed from the study or destroyed. However, some data collected as part of the study during your enrolment may need to be kept for legal purposes, including, for example, the consent form. If you decide later on to withdraw your consent to participate in this research, you will need to contact the investigators whose names appear at the beginning of this consent form. The study investigators will remove any questionnaire responses and blood test results completed or received before the point of withdrawal. The study investigators will also contact the CITF, which will remove your data from the CITF Database.

Similarly, they will request that investigators in the US destroy your samples. Note that it may not be possible to remove data that have been shared with other researchers, for example, if it has been published. However, we will never publish information that may identify you or your samples.

WILL I BE REIMBURSED FOR PARTICIPATING IN THIS STUDY?

In recognition of the time and effort required to participate in this study, you will receive a $20 e-gift card after each blood test (total $40). The e-gift card will be emailed to you approximately 2 weeks after you complete the study questionnaires.

CONFIDENTIALITY

Your confidentiality will be respected. We will make sure that none of the information collected for the study could directly identify you. Though the consent forms will have your name, all other study documents will be identified using a code that has no relationship to your identity. However, research records identifying you may be inspected in the presence of the Investigator or his designated personnel by representatives of Health Canada and the UBC/Children's & Women's Research Ethics Boards for the purpose of monitoring the research. Information or records that disclose your identity will not be published, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

The requisition to collect your blood sample will include information about you (your name and date of birth) and this information will remain with your blood sample until the samples are analyzed. When the blood samples are analyzed, the data that identifies you is not stored with the results of the data as the blood samples are assigned a code number that does not identify you. Only this number will be used on any research-related information collected about you, so that your identity [i.e. your name or any other information that could identify you] as a participant in this study will be kept confidential. Samples will be stored in secured, restricted-access laboratories. Some analyses for this study will be done in the US. To protect your identity, these samples will be de-identified prior to sending them to the US. No personal information that can directly identify you will be transmitted to the US. However, despite these measures, any study samples sent outside of Canadian borders may carry a small risk of inadvertent disclosure of information because the laws dealing with protection of information may not be as strict as in Canada. By signing this consent form, you are consenting to the transfer of your de-identified samples, to organizations in the US, for the purpose of the analyses described in this form.

Personal information about your identity, for example the list that matches your name to the coded number that is used on your research-related information, will remain only with the Principal Investigator and/or designated personnel at BC Children's Research Institute at the University of British Columbia. This list will not be removed or released without your consent unless required by law. However, a copy of your data where we will have removed any information that may identify you will

be shared with the CITF. Your identifying information will NOT be provided to the CITF, nor included in the CITF Database. Your identifiers, such as your name and civic address, will be replaced with a code that does not identify yourself. Your data in the CITF Database could be used by researchers outside of the province in which you are located, or in other countries following Data Access Committee (DAC) approval. These transfers will also be made in compliance with Canadian law and research ethics. A DAC will be responsible for reviewing applications for access to your data and for approving applications that respect the privacy and access policies of the CITF.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. These laws also give you the right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available upon request.

The blood tests are purely for research purposes and do not have diagnostic utility. Therefore, study investigators will not be able to use these tests to reveal any information about your health. Once the study is completed, your blood samples will be kept for 5 years after the study finishes, as recommended by the University of British Columbia, and will be destroyed thereafter.

WILL ANY OF MY DATA BE MADE AVAILABLE TO THE PUBLIC?

Anonymized or aggregated (i.e. is accumulated with the data of others) data that cannot identify you may be made open to the public using a website that anyone can access.

HOW WILL MY DATA BE MADE AVAILABLE TO RESEARCHERS?

The CITF will share your coded data with researchers in Canada and internationally. Your coded data will be shared with researchers performing for-profit research and non-profit research. The data will be used to perform research concerning COVID-19 and related health outcomes. Your data may be used alone or in combination with the other data we collected as part of this study. The DAC will ask researchers to confirm that their intended research activities have received necessary ethics approvals. Your data may also be shared with other COVID-19 research databases that follow similar protections and procedures as the CITF Database.

RIGHTS AND RESPONSIBILITIES

Consenting to take part in this study does not in any way limit your legal rights against the investigators, or anyone else involved. In addition, by consenting to participate in this study, you do not release the investigators from their legal and professional responsibilities. Your participation in this study is entirely voluntary and your decision will not affect you in any way.

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 email at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll-free: 1-877-822-8598). Please reference the study number H20-03593 when contacting this line.

If you have questions concerning this study, you can contact our study coordinator, Lauren at abcovid@bcchr.ca, or Dr. Pascal Lavoie, the Principal Investigator of the study at: plavoie@bcchr.ca.

CONSENT TO PARTICIPATE

- I have read and understood the information in this consent form.
- I have had enough time to think about the information provided.
- I 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 the 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.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time
- I authorize access to my information and the use of my biological samples as described in this consent 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.

If you want to talk to our study coordinator before you consent to this study, please email Lauren at abcovid@bcchr.ca now, and she should respond to you within 24h. In your email please indicate whether you need a call back, indicating your contact number. Lauren is also available by zoom chat.

Your full name: _____

I have read the above consent form and agree to participate in this study:

☐ Yes
☐ No

Please indicate whether you would be interested in being contacted for future studies conducted by this research team. Note that your answer to this question will not affect your participation and involvement into the current study.

Please select whichever option applies to you:

☐ I agree to be contacted in the future to ask if I am interested in taking part in other studies.

☐ I DO NOT agree to be contacted in the future to ask if I am interested in taking part in other studies.

[A COPY OF THE COMPLETED CONSENT FORM APPEARS]

☐ I certify that all the information in the document above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.