Participant Information and Consent Form (Recovered)
Characterizing Antibody Response to Emerging (CARE) COVID-19

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1. Invitation

You are being invited to take part in this research study, because you are a healthcare worker or other individual who was previously diagnosed with and have recovered from COVID-19 infection. The purpose of this study is to learn more about the antibody-specific immune response to COVID-19 in healthcare workers and others in British Columbia.

2. Your participation is voluntary

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving.

Please review the consent document carefully when deciding whether or not you wish to be part of the research and sign this consent only if you accept being a research participant.

3. Who is conducting this study?

This study is being conducted by researchers affiliated with The University of British Columbia, The BC Centre for Disease Control, Vancouver Coastal Health Authority, Providence Health Care and Fraser Health. The study is funded in part by Genome BC Rapid Response Funding and the BC Centre for Disease Control.

4. Background

Most of what we know about the spread of COVID-19 (Coronavirus Disease 2019) around the world has been learned using laboratory tests that look directly at the virus's genetic material called 'RNA'. When someone is suspected of having COVID-19, a sample is taken (from a deep nose swab or a saliva sample). If virus RNA is found in that sample, we assume that person is infected and contagious. Once a person gets better and that virus is cleared, we will no longer be able to see the virus using these tests. Fortunately, virus infections leave behind a signature in the blood called 'virus-specific antibodies' that can be detected using antibody tests – we also call these serological tests.

We can learn a lot about a disease by looking at the antibodies in someone's blood. First, we can learn if someone has been infected with a virus just by looking at the antibodies long after the virus itself has been cleared. We can also learn about what stage of infection someone is in by looking at the different types of antibodies, for example some antibodies are only seen at the beginning of infection while others will be detectable for years or even decades. We can also use antibody tests to measure what level of the population is immune to a virus by screening how many people have antibodies. But first, we have to be confident that the antibody response is effective, because some viruses have ways of escaping or hiding from antibodies. We still don't know enough about COVID-19 to understand how effective our antibody response is to the virus.

In this study we are recruiting 100 individuals that have already been diagnosed and recovered from COVID-19. We want to monitor your antibody response for 3 months and also watch to see if viral RNA appears again over time. This will help us understand if people who have recovered from COVID-19 have a sustained immune response and are capable of safely interacting with other susceptible or COVID-19 positive individuals. For

those who are vaccinated against COVID-19 before or during the study, we will also study the combined impact of vaccination and infection on the antibody response.

5. What is the purpose of the study?

The purpose of this study is to learn more about how the immune system responds to and is sustained in healthcare workers and others who contract COVID-19. We will monitor the antibody immune response and the presence of the virus for three months to determine how the antibody response is maintained and if this correlates with the absence or appearance of virus RNA over time.

6. Who can participate in this study?

You may be able to participate in this study if:

- You were diagnosed as having COVID-19 and you have now recovered from this infection
- You are over 18 years of age and are able to provide informed consent

7. What does the study involve?

Study Visits

If you agree to take part in this study, you will be asked to donate 10 ml of blood (2 teaspoons) and saliva samples at 7 separate visits, 2 weeks apart over 3 months. Each visit will only require 10-15 minutes of your time (excluding travel time). A saliva self-collection kit can be mailed to you if you provide a mailing address at the end of this form or you will be given the option of collecting a kit from one of the study sites. Your samples will be stored securely at the BC Centre for Disease Control.

Medical information

Your samples and test results will be linked to medical information collected in relation to your diagnosis of COVID-19 including your COVID-19 test results, symptoms, symptom onset and severity, level of care required, health authority, if your infection is travel or community acquired, healthcare worker category, as well as your age and sex.

If you have previously participated in a COVID-19 antibody study this year at BC Children's Hospital, we are also asking you to consent to having these antibody test results shared with the researchers of the CARE study for comparison of results between studies.

In addition to accessing medical records related to COVID-19 we are also asking you to fill out a brief checklist of symptoms you experience and the day of their onset at the time of each sample donation. These symptoms will be linked to your antibody and virus test results. Filling out this checklist is optional and you do not have to provide this additional information if you are not comfortable doing so.

The results of your antibody testing will also be added to your personal medical record. Your results may be viewed through your *my ehealth* account or we may mail your results to you if you provide your mailing address at the end of this consent form.

Future Studies

You will be asked if you give us permission to use any of the samples you provide for future COVID-19 related studies. You are free to say yes or no to having your samples used in other research and this will not affect your participation in this study. If you give consent, any sample remaining at the end of this study will be assigned an anonymous, unique code number that will allow your samples to be used anonymously in future research. If you do not allow this, any remaining sample will be destroyed at the end of this study.

If you attend the PHSA collection site at Children's Hospital for your sample collection, there is an opportunity to donate additional blood for future research. Blood would be collected at the same time as your study blood collection and we would not collect more than 30 ml of blood (2 tablespoons) in total. These extra samples will be kept in the BC Children's Hospital BioBank, which acts as a biological library of samples for future research. Your sample will not be made available for other research until this has been discussed with you in more detail and you agree.

Follow-Up

At the end of the study you will be emailed a link to our COVID-19 vaccination survey, which will ask if and when you were vaccinated against COVID-19 along with any symptoms experienced after vaccination.

8. What are the possible harms and discomforts?

The research study requires the collection of blood samples; the risks of blood draw include mild pain or discomfort and bruising and the rare possibility of infection.

9. What are the potential benefits of participating?

There may not be a direct benefit to you from taking part in this study. However, a potential benefit is that you may be identified as having developed an antibody response to COVID-19. You will also be aiding the BC Centre for Disease Control to validate screening procedures for antibody responses to COVID-19 and aid in understanding the immune response to SARS-CoV-2 (the virus that causes COVID-19) infection. This may be of indirect benefit to you because the information will be used to guide the public health response to COVID-19 and may be used to identify healthcare workers with immunity that can become the main task force attending the COVID-19 crisis.

10. 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, you have the right to request the withdrawal of your information and/or samples collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn for example where the data 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 and/or samples, please contact the Principal Investigator of this project.

11. How will my taking part in this study be kept confidential?

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator, or his or her designate, by representatives of The BC Centre for Disease Control, Health Canada, or the UBC Clinical Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned 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 your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator, Medical Health Officer or other Medical or Laboratory personal who have routine access to medical information and protect patient confidentiality as a condition of employment. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. You also have the legal right of access to the information about you and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to the Principal Investigator of this study. Your personal information or information that could identify you will not be revealed without your express consent unless required by law.

12. What will the study cost me?

The research-related blood draws and respiratory sample collections required for your participation in this study will be provided at no cost to you, however you will be required to arrange transportation to and from sample collection sites.

You will receive a $50 gift card as a token of our appreciation for your participation in this study. In the long-term, if a research, diagnostic or therapeutic product or service is developed, you will not receive a financial benefit.

13. Who do I contact if I have questions about the study during my participation?

If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact the Principal Investigator of this project, Dr. Muhammad Morshed at (604) 707-2622 or contact the study team at CAREstudy@bccdc.ca.

14. Who do I contact if I have any questions or 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). For Fraser Health Participant concerns please contact the Fraser Health Research Ethics Board Co-Chair at 604-587-4681. Please reference the study number H20-01089 when calling so the Complaint Line staff can better assist you.

8. Participant Consent: Characterizing Antibody Response to Emerging (CARE) COVID-19

My signature on this consent form means:

- 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 authorize access to my health records related to COVID-19 as described in this consent form.
- 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, and that this will not change the quality of care that I receive.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I will receive a signed copy of this consent form for my own records.

I consent to participate in this study: ☐ Yes ☐ No

I consent to sharing previous COVID-19 antibody study results with the CARE study team: ☐ Yes ☐ No ☐ N/A

I agree that any leftover blood samples can be used for future COVID-19 related research. I recognize that I can withdraw any remaining blood or saliva samples at a later date and request that these be destroyed: ☐ Yes ☐ No

I agree to have additional blood collected for future research and agree to be contacted by BC Children's Hospital BioBank to discuss use of these samples: ☐ Yes ☐ No ☐ N/A

I agree to have a self-collection kit and a paper copy of my COVID-19 serology results mailed to me: ☐ Yes ☐ No

Mailing address: _____

Street City Province Postal code

I agree to be contacted in future about related research studies that may be of interest to me. I recognize that I can choose not to participate in future research studies: ☐ Yes ☐ No

Contact e-mail: _____ Optional Phone Number_____

*This email will only be used to contact you regarding this study (e.g. consent confirmation, sample collection reminders, study updates), if you indicated yes above to participating in BC Children's Hospital biobank, and to being contacted regarding future studies. You need to know that emails sent to some webmail services (e.g. Gmail, Hotmail, etc.), may be stored/routed outside of Canada (for example, in the United States) and governed by foreign laws. Due to the fact that future emails will contain personal information about you, including your name and information about your health, the Freedom of Information and Protection of Privacy Act requires that we obtain your consent before we continue. All of the information

which you provide to us will be kept completely confidential. Providing your email address means that you voluntarily agree and give your consent for the study team to use email to communicate with you.

Participants Signature

Participant's Signature	Printed name	Date

Signature of Person Obtaining Consent	Printed name	Study Role	Date

Investigator Signature

Investigator Signature	Printed name	Date

My signature above signifies that the study has been reviewed with the study participant by me and/or by my delegated staff. My signature may have been added at a later date, as I may not have been present at the time the participant's signature was obtained.