



PARTICIPANT'S CONSENT FORM 1

An Assessment of Serologic Evidence of COVID-19, Social and Occupational Contacts in Health Care Workers in a Sample of Long-Term Care and Acute Care Facilities in South Eastern Ontario-Score Study

INVESTIGATORS:

Name	Role	Data Access
Jorge Martinez-Cajas, MD FRCPC Department of Medicine	Principal Investigator	Collection, use, analysis, dissemination, retention, and disposal
Yanping Gong MD, PhD, FRCPC, Department of Pathology and Molecular Sciences	Co-Principal investigator	Use, dissemination
Kristin Sabourin, MSC	Research Assistant	Collection, Analysis, dissemination
Kieran Moore MD, CCFP, MPH, FRCPC, Medical Officer of Health, Chief Executive Officer, KFL&A Public Health	Co-investigator	Collection, dissemination
Beatriz Alvarado-Llano, MD, PhD Public Health Sciences	Co-investigator	Collection, use, analysis, dissemination, retention, and disposal
Christian Muise, PhD Assistant Professor, Computing Sciences	Co-investigator	Use, analysis, dissemination
Gerald Evans, MD FRCPC Professor, Department of Medicine	Co-investigator	Analysis, dissemination
Anne Ellis, MD, MSc, FRCPC, FAAAAI, Professor Department of Medicine	Co-investigator	Collection
Prameet M. Sheth MSc. PhD. D(ABMM), F(CCM). Director of Molecular Microbiology	Collaborator	Analysis, dissemination

You are being invited to participate in a research study that seeks to understand how antibodies against the SARS coronavirus -2 (SARS-CoV-2) affect the risk of transmission of COVID-19 in healthcare facilities in South Eastern Ontario and how health care worker's activities inside facilities and community may impact such a risk. The main objectives of this project are: 1) To measure the proportion of health care workers (HCW) who have neutralizing antibodies against the SARS-CoV-2 spike protein in the participating facilities; 2) to describe occupational and social contact patterns of HCW and; 3) to devise possible strategies where the presence of antibodies against SARS-CoV-2 in HCW can be used as a factor to reorganize care in Long term care facilities- LTC, that contributes to reduce the risk of subsequent COVID-19 outbreaks.

Your involvement in this study includes A) the completion of an online-questionnaire; B) provision of blood samples, one at the beginning and one at the end of the study (9-12 months), C) completion of a social contact diary; D) short monthly surveys to monitor exposure to or acquisition of COVID-19 and; E) providing permission to contact you regarding consenting related to contact tracing data.

The questionnaire will ask about your health and occupational history, and exposure to COVID-19 at work and in the community. This will take about 20 minutes to be completed.

The **blood you provide** will be used to measure the presence of **antibodies against SARS-CoV-2**. This step would require 10-15 minutes of your time. A trained phlebotomist will draw 3 tubes of blood (10 mL in total), which will be processed in a Kingston General Hospital lab. Plasma and serum will be extracted from the blood sample and tested to detect antibodies against SARS-CoV-2. The serum or plasma may be eventually (within two years of completion of recruitment) used to test in the laboratory how well antibodies neutralize the virus. All blood cells will be discarded. Your samples will be frozen and stored only for the purpose of this study at Dr Prameet Sheth Laboratory in the KHSC. No genetic testing will be performed. The results of the test along with an interpretation of them could be given to you upon request to the research assistant at k.sabourin@queensu.ca. A phone call can be arranged with Dr Martinez-Cajas for this purpose.

The **social contact diary** is a short online questionnaire that will inquire about the number and type of contacts you had in a given day. We will ask you to record this over one single day. This day is selected randomly. This survey helps us understand the activities that can be associated with transmission of COVID-19 in the community.

We will send you a **short online survey to complete every month**. This survey will take 5- 10 minutes to complete and its purpose is to follow longitudinally if you have been exposed to or acquired COVID-19 throughout the duration of the study. This information is essential to measure the risk of acquiring COVID-19 over time.

If you have been tested and resulted positive for COVID-19 by nasopharyngeal swab PCR either in the past or throughout the duration of this study, we might need to request additional consent from you to extract some data from the public health unit that conducted the **contact tracing** associated with your case. At this point you are providing us consent to contact you again for the purpose of requesting additional consent should these data be needed in your case.

Risks associated with the research project

The blood test may cause some discomfort and bruising due to the needle puncture. This will be minimized by hiring highly experienced phlebotomists.

There is a risk of breach of confidentiality of health care information when obtaining and transferring data kept by the public health unit, which will be minimized following secure data abstraction and transfer procedures which include data anonymization, file encryption and use of secured data servers.

To minimize the risk of breach in privacy of the blood samples, secure transportation procedures will be in place, following standards of KHSC laboratory.

There is also a remote possibility that during your research activities you could come into contact with someone with COVID-19. If this highly unlikely event were to occur, we are required by the Public Health Unit to retain on file your email address or phone number to share with them for contact tracing purposes.

Benefits

There are not direct benefits for participating in this study. This study results will help us understand the risk of acquisition of COVID-19 in people who have recovered from COVID-19 and whether the presence of antibodies against the SARS-CoV-2 modifies such a risk during subsequent waves of the epidemic. It will also provide us with an understanding about how HCW activities could impact the risk of COVID-19 transmission within health care facilities and between these and the community.

Voluntary participation and possibility to withdraw

Your participation in this research project is voluntary. You are therefore free to refuse to participate in this research study without penalty, loss of benefits or impact on your employment standing. You can withdraw at any time by letting us know that you wish to do so. However, the information collected up to the time of withdrawal will continue to be used for this research. In addition, the samples already collected before the withdrawal date will continue to be used for the study. To withdraw from the study please contact k.sabourin@queensu.ca or me: jm209@queensu.ca.

Confidentiality

During your participation in this project, the researchers will collect and record the information using a secure platform only accessible via a password by the main investigator and two other designated researchers. Plasma and serum aliquots obtained from the blood samples will be labeled with a unique sample ID number that we will e-mail you or text you by phone. Once the results are known, we will enter and link the results in our database using your study ID which is different from your sample ID, effectively anonymizing the sample result within the database.

All collected information will remain strictly confidential to the extent prescribed by the law. To protect your identity and the confidentiality of this information, an alphanumeric code will be generated and used instead to link your dataset. The code linking your name to your study file will be kept for 5 years after study completion by the principal investigator (Dr Martinez-Cajas) in a secured, locked location after which we will destroy it along with all research data. The samples with a positive result for COVID-19 antibodies will be kept for up to two years from completion of recruitment. The samples that are negative will be discarded within a week of testing.

Any data published in academic journals, and/or shared by other individuals during scientific meetings will NOT identify any individual that participated in this study.

Compensation

There is no compensation for participating in this study.

PARTICIPANT STATEMENT AND SIGNATURE SECTION

I have read and understood the consent form for this study. I have had the purpose, procedures and technical language of this study explained to me. I have been given sufficient time to consider the above information and to seek advice if I chose to do so. I have had the opportunity to ask questions which have been answered to my satisfaction. I am voluntarily signing this form. I will receive a copy of this consent form for my records. I have not waived any legal rights by consenting to participate in this study.

If at any time you have questions, you can contact Kristin Sabourin at 1-343-580-5550 or **Dr Jorge L Martinez-Cajas at (1) 613-533 6000 ext 75471. If you have questions regarding your rights as a research participant, you can contact Dr. Albert Clark, Chair, Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board at (1) 844-535-2988 or HSREB@queensu.ca**

The Research Ethics Board is required to do a periodic review of ongoing research studies. As part of this review the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB) may require access to the study research records to monitor the ethical conduct of the research

By clicking below, I am verifying that: I have read the Letter of Information and I consent to participate in this research study:

☐

Funding of the research project

The researchers in charge of the project received funding from the PSI foundation.

Conflicts of Interest:

The investigators disclose no conflicts of interest.