Letter of Information and Consent to Participate in a Research Study

Title of Research Study:

The COVENANT Study: COVID-19 Cohort Study of People Experiencing Homelessness in Toronto

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Study personnel can be reached from Monday to Friday, 9:00 am – 5:00 pm.

Funding

This study is funded by the COVID-19 Immunity Task Force (CITF). The investigators have no conflicts of interest to disclose.

Introduction

You are being asked to consider taking part in a research study because you are currently experiencing homelessness. Before agreeing to take part in this research study, it is important that you read the information in this research consent form. It includes details we think you need to know in order to decide if you wish to take part in the study. If you have any questions after you read through this form, please ask the research team. You should not sign this form until you are sure you understand all the information on the form. Participation in this study is voluntary.

Purpose of the Research

The purpose of this study is to collect information on COVID-19 among people experiencing homelessness. Homelessness puts people at high risk during the COVID-19 pandemic. This study will provide important information on the spread of COVID-19 in the homeless population. This information may help support the health of people experiencing homelessness during the pandemic.

For this study, we will be recruiting 700 study participants from shelters, hotel programs and homeless encampments in Toronto, and then following-up with participants every 3 months for one year.

Description of the Research Activities

If you consent to participate in the study, you will be asked to participate in a total of 5 interviews: one interview today and then one interview every 3 months for the next year. We will ask you questions such as demographics, housing history, and questions about your thoughts and experiences with the COVID-19 vaccine. At the time of each interview you will also be asked to provide a saliva sample, where you will swish and gargle a solution for a period of time then spit into a cup, and a finger-prick blood sample (where we take a few drops of blood from your finger). At the interview today, you will also be asked to provide a second saliva sample by chewing on a swab. (Please note that using saliva samples to test for COVID-19 is not the standard method in Ontario. If you receive a positive test result, you will be asked to have a nasopharyngeal (NP) swab test to confirm the results.) The saliva and blood samples will be sent to research labs at Mt. Sinai Hospital and The University of Toronto, where scientists in the lab will test the saliva to see whether you currently have the COVID-19 virus, and will test the blood sample to see if you have antibodies to COVID-19, which would indicate if you have had COVID-19 in the past. These antibodies are substances that the body makes in response to infection with COVID-19. Please note, having antibodies does not necessarily mean you have developed immunity or are resistant to COVID-19. It simply means you were probably exposed to the virus at some point in the past. If you would like to receive the results of your antibody tests at the end of the study, we will call you after your last interview to give you the information. The interviews will take approximately 30-45 minutes to complete.

We also ask that you call a toll-free study number around 1 month before each interview to provide us with any updates to your contact information.

Other Research Activities

In addition to collecting information from you directly, with your permission, we would also like to collect additional information from the sources listed below and explained in detail at the end of this letter. You will be asked to consent specifically to each of these and may opt out if desired.

1) Health-related information from ICES
2) Shelter use information from the City of Toronto's Shelter Support & Housing Administration Division
3) Contact information of friends, family, and service providers
4) Permission to contact you for related research studies in the future
5) Permission to obtain any positive COVID-19 test swab from the laboratory and look at the COVID-19 virus's genetic fingerprint. We will only be looking at the genetic material of the COVID-19 virus, NOT your DNA.

Your health card number, name, date of birth, and gender/sex listed on government documents will be securely transferred from St. Michael's Hospital to the Institute for Clinical Evaluative Sciences (ICES) to help us gather information about your health, including any health conditions, COVID-19 testing, and hospital use. ICES is an organization where people's health information including health care use in Ontario is stored. The information will be securely

provided to the research team by ICES as coded information only for analysis. Any personal identifiers such as your health card number or name will be removed or replaced with a code that is not known to the research team.

Your name, date of birth, and gender/sex will be securely transferred from St. Michael's Hospital to the Shelter Support & Housing Administration Division to obtain information about your use of shelter programs in Toronto. For example, if you move to stay at a shelter program different from your current location, we will be notified of this information. These data will cover a period of one year before you join the study and will go up to two years after you have joined the study. Your name, date of birth, and gender/sex will also be used to help the research team locate you for upcoming interviews.

If you consent, we will obtain any positive COVID-19 test swabs from the laboratory and look at the COVID-19 virus's genetic fingerprint. Your sample will be transported from the original testing laboratory to the Sinai-UHN laboratory. A technician will extract genetic material from the virus that will be sent for sequencing at a CANCOGEN-partnered sequencing facility. The original sample will be stored for up to 10 years and then destroyed. We will only be looking at the genetic material of the COVID-19 virus, NOT your DNA. This allows us to examine the COVID-19 virus that infected you, test for variants, and track outbreak and infections patterns in different settings. This type of testing is routinely done by public health units to track the COVID-19 virus.

Potential Risks

Some of the interview questions may seem personal and may make you feel uncomfortable or may upset you. If this happens, you do not need to answer any question that you do not wish to, and you can let the interviewer know if you would like to take a break or stop the interview.

The main risk to participants is detection of active COVID-19 infection through study testing. Participants with a positive test will be contacted directly or by shelter staff to be informed of their status and offered temporary shelter, health monitoring, and supports at specially designated recovery shelters operated by the city of Toronto. Your name and results will be shared with the shelter staff for the purpose of notifying you of your results and connecting you to a service operated by the City of Toronto for people experiencing homelessness to recover from COVID-19. Your name and results will also be shared via email and Hypercare with the City of Toronto to facilitate transportation to a recovery site. You will be offered to have a driver meet you at the shelter you are residing at and take you to a COVID testing centre for confirmatory testing. They will then take you to a recovery site for you to stay at while you wait for your test results and/or recover from COVID-19. Given that COVID-19 is a condition of public health significance, positive results will be reported to the Medical Officer of Health (also known as Toronto Public Health), under the Health Protection and Promotion Act. Additionally, the Ontario government has passed a regulation authorizing first responders, such as police, firefighters and paramedics to access an individual's name, address, date of birth and whether the individual has had a positive test for COVID-19. It is unknown how long these regulations will be in place.

Potential Benefits

The main benefit to participants is the opportunity to find out about your COVID-19 status. If you do test positive, our research team will help you obtain referral and transportation to sites for confirmatory testing, temporary shelter, support, and health monitoring.

Protecting Your Health Information

All persons involved in the study are committed to respecting your privacy. No persons other than select members of the research team will have access to your personal health information without your consent, unless required by law. Study personnel will make every effort to keep your personal health information private and confidential in accordance with all applicable privacy legislation, including the Personal Health Information Protection Act (PHIPA) of Ontario.

To maintain your privacy, any personal information is kept separate from your study data and given a code. Your survey responses will not include any personally identifying information. Your survey data will be collected by trained interviewers using tablets and no data is saved on these tablets. Once collected, the data will be securely sent, stored, and kept at St. Michael's Hospital's on a secure computer server. All specimens, including saliva and finger-prick blood samples will be identified with a code. Our understanding of COVID-19 is changing rapidly. To allow for possible future research on COVID-19, all study data and samples will be kept for a period of 10 years following the end of the study and then destroyed.

Despite these protections, there remains a risk of unintentional release of information. However, the Principal Investigator will protect your records and keep your information confidential to the greatest extent possible. The chance that your personal information will be unintentionally released is very small.

Data Sharing with the COVID-19 Immunity Task Force (CITF)

The CITF is a national initiative funded by the Government of Canada to perform research related to COVID-19 immunity. Your study data related to COVID-19 infection status, demographic information, health, experience with COVID-19, activities and behaviors related to COVID-19, and housing history will be shared with the CITF. However, all of your study data will be labelled with a code and not with your personal information. No personally identifying information will be shared with the CITF.

Data provided to the CITF will be stored in the CITF database. The CITF database will be held under the custodianship of McGill University or one of its collaborators and will be shared via the cloud, both nationally and internationally. Data in the CITF database will be stored indefinitely, until it is no longer useful for research, or until an ethics committee decides otherwise. The data in the CITF database might be accessed by other researchers studying COVID-19 following approval by a Data Access Committee. This Committee will ensure that all use of data stored in the CITF database is in full compliance with Canadian law and research ethics.

Email and Text Message Communication

We may contact you by email or text message, if you indicate that you would like to be contacted this way when we collect your contact information. There is no obligation to text or email – you may always contact us by phone. Please note that email and texting may not be secure modes of communicating, since they may be viewed by others and kept indefinitely. For these reasons, we will use email and text messaging to set up appointments, but we will not include personal health information such as your full name, date of birth, or OHIP number in emails and text messages.

There are common risks of using email to communicate including:
• Information travels electronically and is not secure in the way a phone call or regular mail would be.
• If someone sees these messages they may know that you are a participant in this study or see the health information included in the message.
• Emails and text messages may be read or saved by your internet or phone provider (i.e. Rogers, your workplace, "free internet" providers).
• Copies of an email or a text message may continue to exist, even after efforts to delete the email have been made.
• There is always a chance with any unencrypted email or text message, however remote, that it could be intercepted or manipulated.

Please note: YOU MUST NOT USE EMAIL OR TEXT MESSAGES FOR MEDICAL EMERGENCIES. If you require immediate help, call your clinic or care provider, or seek emergency services.

Limits to Confidentiality
Any information that reveals your identity will not be released without your consent, unless required by law. COVID-19 is a reportable disease by law, so positive tests will be reported to Toronto Public Health. If you do have a positive test result, we will work with you, Toronto Public Health, and/or the place you are staying to help you get appropriate care and support. Positive tests are the only piece of data in this study that will be released to Toronto Public Health with your name.

Publication of Study Results
The results of this study may be presented at scientific conferences or published in scientific journals. If you are interested in obtaining the results of the study, you can contact the Principal Investigator or Research Coordinator by phone or email. You will never be personally identified in any publication, report, or presentation that may come from this study.

Potential Costs and Reimbursement
If you agree to participate in the study, you will receive $40 after each sample collection and interview (up to $200 for completing all 5 interviews) to compensate you for your time and help with transportation costs for follow-up interviews. In addition, you will have the opportunity to call the research team one month before each scheduled interview to update your contact information and confirm the timing of your next interview. You will receive $10 for each check-in call (up to $40 for completing all 4 check-ins). This additional $10 will be provided at your next interview.

Participation and Withdrawal
Participation in this study is completely voluntary. Even if you choose to participate, you may change your mind and stop participating in the study at any time without giving a reason. A researcher may ask you if you would like to re-join the study from time to time, but the decision is yours. You are not obligated to re-join the study. If you choose to withdraw from the study, the data and samples collected from you prior to your withdrawal will be retained and used in analyses.

Your decision to participate or not, or to withdraw from the study, will not impact the services you access from St. Michael's Hospital or any other service provider. If anything about the study changes that may impact your desire to participate, it will be communicated to you immediately.

Research Ethics Board Contact

If you have any questions regarding your rights as a research participant, you may contact the Unity Health Toronto Research Ethics Board Office at 416-864-6060 ext. 2557 during business hours (9:00am-5:00pm) Monday to Friday.

The study protocol and consent form have been reviewed by a committee called the Research Ethics Board. The Research Ethics Board is a group of scientists, medical staff, and individuals from other backgrounds (including law and ethics) as well as members from the community. The Board is established to review studies for their scientific and ethical merit. The Board pays special attention to the potential risks and benefits to the participant, as well as the potential benefit to society.

Study Contacts

If you have any questions about this study, contact Olivia Spandier, the study coordinator, at St. Michael's Hospital at 416-864-6060 ext. 77440. You may also contact Dr. Stephen Hwang, the Principal Investigator, at 416-864-5991.

Richard L, *et al. BMJ Open* 2022; 12:e063234. doi: 10.1136/bmjopen-2022-063234

Signature Pages: Documentation of Informed Consent
The COVENANT Study: COVID-19 Cohort Study of People Experiencing Homelessness in Toronto

By signing this consent form, I acknowledge that:

- I have received a copy of this letter of information and consent form.
- This research study and the information and samples to be collected from me have been explained to me, and my questions have been answered to my satisfaction.
- I know that I have the right not to participate and the right to withdraw from this study without affecting the services I receive at St. Michael's Hospital or any other service provider.
- The potential risks and benefits of participating in this research study have been explained to me.
- I have been told that I have not waived my legal rights nor released the investigator or involved institutions from their legal and professional responsibilities.
- I know that I may ask, now or in the future, any questions I have about this study.
- I have been told that information about me and my participation in this study will be kept confidential and that no personally identifying information will be disclosed without my permission unless required by law.
- I have been given sufficient time to read the information in this consent form.

I consent to participate in this study.

Participant Name (Print)	Participant Signature	Date

I have explained to the above-named participant the nature and purpose, the potential benefits, and possible risks of participation in this research study. All questions that have been raised about this study have been answered.

Name of Person Obtaining Consent (Print)	Position/Title of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

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CONSENT TO THE RELEASE OF INFORMATION FROM ICES

I consent to the research team linking my provincial health card number, my name, gender/sex, and date of birth to Ministry of Health files to obtain information about my health such as healthcare use, health conditions, and COVID-19 testing for the past 10 years and next 5 years.

☐ Yes _____ (initials) ☐ Declined

CONSENT TO THE RELEASE OF INFORMATION FROM THE CITY OF TORONTO

I consent to the transfer of my name, date of birth, and gender/sex to the City of Toronto's Shelter Support & Housing Administration Division in order for them to provide information to the research team about my use of the shelter system in Toronto and to locate and contact me for upcoming interviews.

☐ Yes _____ (initials) ☐ Declined

CONSENT TO THE RELEASE OF INFORMATION BY CONTACT PERSONS

I consent to the research team contacting the individuals I have listed as alternate contacts when attempting to contact me for the purpose of conducting follow-up interviews. This may include contacts at social services agencies I frequent or other people who might know where I am. I authorize these people to release information regarding my up-to-date contact information and location to the research team.

☐ Yes _____ (initials) ☐ Declined

CONSENT TO CONTACT FOR FUTURE RELATED RESEARCH STUDIES

The study team may wish to contact you regarding additional research related to this study. You are under no obligation to participate in additional research if contacted. I give permission for the research team to contact me regarding participation in additional research. Your contact information will be kept on a secure server at St. Michael's Hospital.

☐ Yes _____ (initials) ☐ Declined

CONSENT TO SHARE COVID TEST SAMPLES

If you have had COVID-19 or if you get it in the future, do you give the study team permission to obtain your positive test swab from the laboratory and look at the COVID-19 virus's genetic fingerprint. We will only be looking at the genetic material of the COVID-19 virus, NOT your DNA.

☐ Yes _____ (initials) ☐ Declined

INTEREST IN RECEIVING BLOOD TEST RESULTS AFTER THE STUDY

I would like the research team to contact me by phone to let me know the results of my blood tests after the study has ended.

☐ Yes _____ (initials) ☐ Declined

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If participant is not able to read independently for any reason:

Declaration of Assistance – Witness to Consent Process

Study Participant's Name (Print): _____

ASSISTANCE DECLARATION AND SIGNATURE:
I have provided assistance during the consent discussion between the potential participant and the person obtaining consent by (please check one):

- ☐ Acting as a witness to the consent discussion
- ☐ Assisting in delivery of consent discussion (reading/oral), including communication of questions and responses
- ☐ Other: _____

I attest that the information was accurately explained, and the participant has freely given consent to participate in the research study.

Name of Person Assisting Consent (Print)	Signature of Person Assisting Consent	Date	Time

Relationship to Study Participant: _____

Contact Information of Person Assisting Consent: _____

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If participant has limited proficiency in English:

Declaration of Assistance – Interpreter

Study Participant's Name (Print): _____

INTERPRETER DECLARATION AND SIGNATURE:
I am competent in the English language and in the preferred language of the potential participant: _____ (name of language)

I am not involved in the research study or related to the participant. I agree to keep confidential all personally identifying information of the participant. I have faithfully interpreted the consent discussion and provided a sight translation of the written informed consent form as directed by the research staff obtaining consent.

_____	_____	_____	_____
Name of Interpreter (Print)	Signature of Interpreter	Date	Time

Contact Information of Interpreter: _____

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