

Letter of Information and Consent to Participate in a Research Study



Title of Research Study:

A Qualitative Exploration of Vaccine Uptake and Hesitancy Among People Experiencing Homelessness

Principal Investigator

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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 Canadian Institutes of Health Research (CIHR). 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 contextualize the experiences of those experiencing homelessness during the COVID-19 pandemic. Homelessness puts people at high risk of contracting COVID-19. As according to an Ontario study, people experiencing homelessness are 20 times more likely to be hospitalized with COVID-19, 10 times more likely to end up in intensive care. Vaccination is one effective approach to protecting communities and populations from infection of COVID-19 as well as other strategies individuals utilize to keep safe.

This study aims to better understand the individual, community and structural drivers of COVID-19 vaccine uptake and hesitancy of those experiencing homelessness and other strategies that people employ to protect themselves and their communities. This study invites people experiencing homelessness to offer their thoughts and experiences, in order to address vaccination hesitancies as well as informing and supporting community agencies that work to protect those experiencing homelessness during the COVID-19 pandemic.

This study will also help future crises responses, allowing public health decision-makers identify strategies to provide those experiencing homelessness when public crises occur.

This is a sub-study of the COVENANT cohort study that looks at the prevalence of COVID-19 amongst those experiencing homelessness for over a 12-month period; participants may be recruited to participate in the main study as well as this sub-study.

Inclusion and Exclusion Criteria

For this study, we will be recruiting 40 study participants (ages 18 and up) from shelters, hotel programs and homeless encampments in Toronto, all of whom identify as homeless at the time of recruitment. Some participants may be a part of the main COVENANT cohort study and some may not.

Individuals who are not able to provide consent will be excluded from this study.

Description of the Research Activities

Interview:

You are being asked to participate in an interview discussing your thoughts about the COVID-19 vaccine, any barriers to vaccination or strategies you think could help improve vaccination among people experiencing homelessness. We are also interested in other strategies you use to stay safe during this pandemic, strategies to protect yourself and/or your community members. Interviews may last between 45 minutes and 1.5 hours, and can be conducted in person or over the phone or over zoom (the audio will be recorded but not the video nor transcript).

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.

If the interview is conducted over the phone or zoom, the consent form will be sent via email, there are important privacy considerations to be aware of. *There are common risks of using email to communicate:*

- Information travels electronically and is not secure in the way a phone call or regular mail would be.
- If someone sees these emails they may know that you are a participant in this study or see the health information included in the email.
- Emails may be read or saved by your internet or phone provider (i.e. Rogers, your workplace, “free internet” providers).
- Copies of an email may continue to exist, even after efforts to delete the email have been made.
- There is always a chance with any unencrypted email, however remote, that it could be intercepted or manipulated.
- Please note: YOU MUST NOT USE EMAIL FOR MEDICAL EMERGENCIES. If you require immediate help, call your clinic or care provider, or seek emergency services.

Potential Benefits

There are no direct benefits for those who participate in this sub-study. However, this study has multiple indirect benefits. Information that we learn from you and others will help researchers identify ways that government responses to crises can improve to better support people experiencing homelessness. Specifically, the strategies we identify together to overcome barriers to vaccination, and other strategies you are using to stay safe during the pandemic, will be shared with groups working to improve responses to the COVID-19 pandemic and other health crises that may arise in the future.

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. Interviews will be recorded using a password protected audio recorder and uploaded to an encrypted USB. Once collected, the data will be kept on the encrypted USB and securely sent, stored, and kept at St. Michael's Hospital's on a secure computer server.

Interviews will be transcribed word for word (excluding any identifying information such as names, specific locations, or identifying details of stories). After data analysis is completed the data will be destroyed from the encrypted USB and kept only and securely on a St. Michael's Hospital secure computer server for five years after which it will be 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. Any information that reveals your identity will not be released without your consent, unless required by law.

Publication of Study Results

The results of this study may be presented at scientific conferences, shared at a town hall or published in scientific journals. 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 the completion of the interview to compensate you for your time. If you complete this interview over the phone or zoom, you have the option of receiving an e-transfer of the honorarium. In order to do this, we will need your email address and consent to send you an e-transfer. You may also collect it in-person, or have a cheque mailed to you.

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.

If you decide to withdraw from participation of the study during the interview, you will still receive an honorarium for your time. Additionally, you will be granted a two-week grace period of whether or not you would like to withdraw from the study. The grace period will be effective

immediately after the conclusion of the interview. After the grace period concludes, data will be de-identified and analysis will have begun.

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 Jesse Jenkinson, the study co-investigator, at St. Michael's Hospital at jesse.jenkinson@unityhealth.to or 647-785-6900. You may also contact Dr. Stephen Hwang, the Principal Investigator, at 416-864-5991.

Signature Pages: Documentation of Informed Consent**A Qualitative Exploration of Vaccine Uptake and Hesitancy Among People Experiencing Homelessness**

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 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
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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 share contact information to receive study results:

If you are interested in obtaining the results of the study, you can contact the Principal Investigator or Research Coordinator by phone or email. If you would like the study team to contact you, please provide email or phone number that the study team will use to contact you to share study results.

I consent to have the study team contact me by email or phone to share study results.

Initials: _____

Phone: _____

Email: _____

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
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Relationship to Study Participant: _____

Contact Information of Person Assisting Consent: _____

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: _____