Information Letter
Consent to Participate in a Research Study

Title of Research Project: Wellness Hub: Understanding COVID-19 Transmission through Implementing and Evaluating an Intervention to Support Wellness, IPAC, Vaccine Uptake, and other Wraparound Care Needs in LTCH/RHs.
Short Title: Wellness Hub

Study Component: Needs Assessment Interviews

Nominated Principal Investigator:
Sharon E. Straus, MD MSc FRCPC, Director of Knowledge Translation Program
St. Michael's Hospital, Professor, University of Toronto, Email: Sharon.Straus@unityhealth.to
Tel: (416) 864-3068 (available Monday to Friday, 9am to 5pm)

Co-Principal Investigators:
Allison McGeer, MD MSc FRCPC, Microbiologist, Infectious Disease Consultant, Mount Sinai Hospital, Email: amcgeer@mtsinai.on.ca (available Monday to Friday, 9am to 5pm)

Christine (Tina) Fahim, PhD, MSc, Scientist, Knowledge Translation Program, St. Michael's Hospital, Email: Christine.Fahim@unityhealth.to, Tel: (416) 360-4000 ext. 77300 (available Monday to Friday, 9am to 5pm)

Sharmistha Mishra, MD, PhD, Scientist, Li Ka Shing Knowledge Institute, St. Michael's Hospital, Email: Sharmistha.Mishra@unityhealth.to (available Monday to Friday, 9am to 5pm)

Stefan Baral, MD, FRCPC, CCFP, Associate Professor, Department of Epidemiology, John Hopkins School of Public Health, Email: sbaral@jhu.edu (available Monday to Friday, 9am to 5pm)

Adrienne Chan, MD, MPH, FRCPC, Affiliate scientist, Evaluative Clinical Sciences, Veterans Research Program, Sunnybrook Research Institute, Email: adrienne.chan@sunnybrook.ca, Tel: 416-480-6100, ext. 6044 (available Monday to Friday, 9am to 5pm)

Selected Study Personnel:
Jamie Boyd, MSc, Research Manager, Knowledge Translation Program St. Michael's Hospital, Email: Jamie.Boyd@unityhealth.to, Tel: (416) 864-6060 ext. 77042 (available Monday to Friday, 9am to 5pm)

Study Sponsor: Knowledge Translation Program, St. Michael's Hospital
Study Funding: COVID-19 Immunity Task Force, John and Myrna Daniels Charitable Foundation via the University of Toronto's Aging and Place Institute

Conflicts of interest: The nominated and co-principal investigators and research staff do not have any conflicts of interest, financial or otherwise, related to this study or its outcome.

We are inviting you to participate in a Needs Assessment Interview because your long-term care home (LTCH)/retirement home (RH) is currently participating in the Wellness Hub research program, a research program to support LTCHs and RHs during the COVID-19 pandemic.

As a part of your LTCH/RH's participation in this program, you are invited to complete an interview to highlight the current COVID-19 related challenges you are experiencing at your facility to inform the content of the Wellness Hub support program.

Participation in the Study
This Needs Assessment Interview is voluntary. You do not have to participate if you do not want to, and if you do, you can withdraw at any time. If you choose not to participate, there will be no impact to the medical care received, employment at, or other relationship with Unity Health or your LTCH/RH now or in the future for you and your family. Your decision to participate or not will not impact your LTCH/RH's participation in the Wellness Hub research program. You will still be able to receive any supports provided with the research program (e.g., facilitator support).

At this point, please also engage an interpreter and/or other witness to the consent process if you require support with working through the content of this consent form.

Before agreeing to take part in this research study, it is important that you read this Information Letter. 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, you can ask an investigator or research team member using the contact information listed above. Please feel free to discuss the study with others, such as a family member and/or a close friend.

What are the objectives of this research study? In Canada and worldwide, LTCH/RHs have faced challenges with preventing and managing outbreaks of COVID-19. Our team is conducting a study to 1) implement a program to support the uptake of best practices in wellness, infection prevention and control (IPAC), as well as to support the uptake of vaccine confidence and wraparound care supports in LTCH/RHs, and 2) understand the spread of COVID-19 infection in the LTCH/RH population. To do this, we hope to estimate the rate of individuals who previously had COVID-19 infection, and better understand predictors of previous and future COVID-19 infection.

Who will be involved in this component of the research study?

72 LTCH/RHs will be invited to participate in the Wellness Hub research program, 48 of which will be receiving the Wellness Hub support program intervention. We will conduct Needs Assessment interviews with 1-3 key stakeholders from each LTCH/RH receiving the intervention (i.e., homes enrolled in the Facilitated Access arm) who can speak to site-level needs (with the option to include additional team members if deemed appropriate by the home). Depending on the setting, we may also conduct 20 individual-level needs assessment interviews per LTCH/RH to identify individual-level needs and further develop the support program.

Exclusion criteria: Individuals who are under the age of 18 and/or do not speak English or French will not be eligible to participate.

How long will this study last?
Overall, this study will run for 18 months. Your involvement in the research study would involve participating in a Needs Assessment interview at your earliest convenience before the start of the Wellness Hub Support Program.

Description of Research Activities
Participating in a Needs Assessment interview would involve engaging in a 15-20 minute discussion (by phone, videoconference, or in-person) to 1) inform the Wellness Hub program supports, 2) understand how the Wellness Hub Research and Support program can best support your site's needs, and 3) contribute to a greater understanding of the key challenges and opportunities that LTCHs and RHs experienced throughout the pandemic.. The interview will be audio-recorded and notes will be taken throughout.

Potential Risks (Injury, discomfort and inconvenience)

- *Risk:* Some questions asked during the Needs Assessment may make you feel uncomfortable.
    - *Measures taken to reduce risk:* If you find any question or the interview experience stressful, you do not need to answer the question, or you can stop the interview without any consequences to you or your LTCH/RH.
- *Risk:* You may regret sharing some of your responses in the interviews.
    - *Measures taken to reduce risk:* You can contact the study team and remove your interview responses from the data prior to the data analysis stage.

Potential Benefits
Participating in interviews will allow the study team to tailor the support program to ensure that it best addresses your and/or the LTCH/RH's needs and allow us to improve the program moving forward.

Alternatives to Participation
This study is not looking at ways to provide medical treatment to you, so the alternative to taking part in this study is not to take part. Whether you choose to take part in this study or not, there will be no effect on your care or your employment at your LTCH/RH.

Privacy and Confidentiality of Your Personally Identifying Information and Study Data

How will my information be protected?
The study staff are committed to keeping your personal health information confidential in accordance with all applicable privacy legislation, including the Personal Health Information Protection Act (PHIPA) of Ontario.

Who will have access to my identifying information (e.g., name, phone number)?

- No one outside of the study team will have access to your personal health information or identifying personal information without your consent, unless required by law.

How will my privacy be protected?

- If you agree to participate, your LTCH/RH, and any individuals who participate in an interview, will be identified by a participant I.D. number in any data we collect. This includes interview audio-recordings and notes.
- The master linking log, which links I.D. numbers to participant name/LTCH/RH/contact information/identifying information, will be password-protected on the St. Michael's Hospital's secure network and will only be accessible to a subset of the study team.
- Online and/or electronic documentation of consent and study data will be stored on 1) UHT's AHRC RedCap servers for a maximum of 10 years, as well as 2) on a restricted-access shared drive on the UHT secure institutional server for a maximum of 7 years. For RedCap, all study data will be securely stored on local servers at St. Michaels Hospital throughout the duration of the study and for up to 10 years after the study is complete. Authorized personnel receive a username and password which is unique, and database access is controlled by the AHRC (the Data Coordination Centre) in collaboration with the Principal Investigator.In the short term, all hard copy study data will be securely stored by UHT study personnel. In the long term, all hard copy consent forms and study data will be stored in a locked cabinet in a locked room at St. Michael's Hospital for up to 7 years prior to destruction.
- Data may be shared with external researchers according to data sharing protocols (see *Data Sharing of Study Data* below).

- It is important to understand that despite these protections being in place, there is still a risk of unintentional release of information.

How long will my data be kept?

- Audio files will be deleted once the interview notes are analyzed.
- Electronic and hard-copy data will be retained for no more than 7 years, at which point they will be securely destroyed. Study data will be stored on RedCap for up to 10 years after the study is complete.

Will others know what I said or did?

- The results of this study may be shared through a variety of channels at the end of the study, including (but not limited to) LTCH/RH newsletters, scientific conferences, and/or as a published article in a scientific journal. Your name, the name of your LTCH/RH, or any of your personal information, excluding your professional role, will never appear in any presentations or publications that result from this research. Any direct quotations from interviews will be de-identified prior to presentation or publication.

Withdrawal from the Study

- If you choose to take part in this study, you can change your mind without giving a reason, and you may withdraw from the study at any time without any effect on the medical care, employment or other relationship you or your family have at or with your LTCH/RH. If at any time you want to withdraw from this study, please contact a member of the study team. Needs Assessment interview data can be removed up until the point of data analysis. The study may be terminated by the investigators or by the study sponsor at any time for any reason. See *Data Sharing of Study Data* below for specific considerations regarding withdrawal of shared data.

How can I access the results of the research study?

If you are interested in obtaining the results of the study, you can contact the investigators or research team. We estimate that the results of the study will be available in September 2022.

Data Sharing of Study Data

Data Sharing with the CITF:

De-identified versions of these study data may also be shared with our project funder, the CITF, according to their data sharing plan.

- **How long shared with the CITF be stored?** The data on the CITF Database will be stored indefinitely, or, until it is no longer useful for research, or, an ethics committee decides otherwise.
- **Who else will access my data shared with the CITF?** Your data in the CITF Database can be used by researchers outside of the province in which you are located, or in other countries following Data Access Committee (DAC) approval. Data that has either been anonymized (i.e. you cannot be identified), or aggregated (i.e. is accumulated with the data of others), may be made open to the public using a website that anyone can access. Your data may be used alone or in combination with other data, including other health data.
- **How will the data that I share with the CITF be protected?** There remains a minimal risk that the inclusion of your study data in the CITF Database may lead to the disclosure of your identity. This could happen if there is a malicious or inadvertent breach of the CITF Database's security measures.
- **What if I want to withdraw my data?** If you withdraw your consent to participate in this research, we will contact the CITF, which will remove your data from the CITF Database. If some of the data have been shared with other researchers or published, it may not be possible to remove this part of the data.

Data Sharing with Other Investigators:
Study data may also be made available to scientific journals, their reviewers, other researchers inside or outside of Unity Health Toronto, or the public. As a reminder, study data is information that is generated by or collected for a study that has been stripped of personally identifying information.

Additionally, other researchers can submit requests to the study team (NPI) to access the de-identified, anonymized data upon publication submission as per Tri-Council requirements and in keeping with the joint statement on data sharing during public health emergencies.

Potential Costs and Reimbursement
There are no costs to you for participation in this study. You will not be paid for your participation in this study.

New Information about the Research Study
We may make changes to the study as it progresses. We may also learn new things about the study that you may need to know. Some of the new information or changes might affect your decision to continue taking part in the study. You will be notified about any new or changed information in a timely manner and we will ask you if you consent to remain in the study. You may be asked to sign a new consent form at that time.

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. 42557 during business hours (9:00am to 5:00pm).

Unity Health Toronto is a health network that includes Providence Healthcare, St. Joseph's Health Centre, and St. Michael's Hospital. The Unity Health Toronto Research Ethics Board is made up of 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 by Unity Health Toronto to review studies for their scientific and ethical merit. The Board pays special attention to the potential risks and benefits to the research participant, as well as the potential benefit to society.

Study Contacts
If at any time during the study you have questions about the study or the research activities, you should contact the Principal Investigator, Sharon E. Straus at (416) 864-3068 or Sharon.Straus@unityhealth.to.

This letter of information and study protocol has been reviewed by the Research Ethics Board at Unity Health Toronto. The Research Ethics Board may need to review the study records for monitoring purposes. As part of this review, someone may contact you from the Research Ethics Board to discuss your experience during this study.