Letter of Information
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: LTCH/RH Site Participation

Nominated Principal Investigator:
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Selected Study Personnel:
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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 your long-term care home (LTCH)/retirement home (RH) to be one of the sites involved in the Wellness Hub Research Program, a Research and Support Program focused on supporting LTCH and RHs during and beyond the COVID-19 pandemic.

Participation in this program is voluntary. You do not have to participate if you do not want to, and if you do, you can withdraw at any time. 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. If you choose to participate in the study, you will need to provide your consent on behalf of your LTCH/RH once you have finished reviewing all the information.

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 and evaluate 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/RH, and **2)** understand the spread of COVID-19 infection in the LTCH and 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 in Ontario will be invited to participate in the Wellness Hub Research and Support Program, around 48 of which will be able to enroll in the Facilitated Access arm of the Wellness Hub Research and Support Program (i.e., the intervention), and 24 of which will be able to enroll in the Self-Directed Access arm of the Wellness Hub Research and Support Program (i.e., the control group).

What Wellness Hub group will I be placed into?

Each LTCH/RH will be placed in the intervention or control group based on 1) your setting's willingness to receive the facilitator supports, 2) the needs that your LTCH/RH site outlines in your Needs Assessment interview (see below), as well as 3) program capacity.

Exclusion criteria: Conducting research with Indigenous communities must involve partnerships with Indigenous Peoples from developing the research question through to research completion and dissemination to ensure the research is done in a culturally appropriate way and to avoid tokenism. This project has not engaged Indigenous partners from project onset and as such, in keeping with these principles, individuals who self-identify as Indigenous will not be eligible to participate in this study. Guidance from the Indigenous community has stated that engaging Indigenous populations without use of these thoughtful and resourced approaches can be damaging for the Indigenous communities and Indigenous Peoples. There are additional studies COVID-19 studies occurring designed specifically for Indigenous populations which you may be interested in. For more information, please contact our study team, or Olivia Oxlade, Associate Scientific Director at CITF (the study funder) https://www.covid19immunitytaskforce.ca/contact-us/).

Who is leading this research study?

This research is being led by the Knowledge Translation Program at St. Michael's Hospital in Toronto, ON., alongside a team of over 30 collaborators, including the Ontario Long-term Care Association (OLTCA), Family Councils Ontario (FCO), Ontario Ministry of Health and Long Term Care, Infectious disease physicians, LTCH/RH Home leadership (e.g., directors, managers), as well as regional and provincial policymakers.

How long will this study last?

Overall, this study will run for 18 months. The Wellness Hub Research Program activities will be implemented in your LTCH/RH for a maximum of a 12-month period (depending on when you enroll).

Description of Research Activities
If your LTCH/RH participates as a site in the Wellness Hub Program, you be invited to engage in the following activities:

Wellness Hub Program Supports, including:

1. *[If the Healthcare Excellence Canada seed funding recruitment deadline has not passed and/or capacity has not been reached]* Assistance in registering for the Healthcare Excellence Canada (HEC) LTC+ Program seed funding ($10,000) for pandemic preparedness initiatives, and additional educational supports offered through this program.
2. *[If in an eligible geographical region]* COVID-19 saliva gargle testing for PCR COVID-19 diagnosis in symptomatic or high-risk exposure staff, household members, and resident's essential care partners with results in ~24-72 hours.
3. A Weekly Wellness Hub Support Program newsletter.

As well as all supports available to all LTCH/RHs (e.g., Access to educational resources and supports to address needs related to IPAC (IPAC+ branch), staff wellness (CARE+ branch), and vaccine confidence (Vaccine+ branch)).

The 48 homes enrolled in the Facilitated Access arm will additionally have access to:

4. A monthly Wellness Hub Community of Practice (CoP) meeting.
5. Option of additional 1:1 support with goal setting and tailoring and implementation of Wellness Hub program resources from a trained Wellness Hub facilitator. The Wellness Hub team may ask to meet with your site on a regular basis to discuss supports and review how the facilitation program is going.

   To receive these supports, you will also be asked to designate a 'point person' or 'point people' at your LTCH/RH site that can coordinate with the Wellness Hub Research and Support Program team. This 'point person' may be asked to support with data collection activities (e.g., printing hard-copy forms, mailing batches of data with prepaid, pre-addressed envelopes). Finally, as part of your participation in the Wellness Hub study, you may be asked to temporarily store data (e.g., dried blood spot samples, demographic questionnaires) in a secure space in the LTCH/RH.

   Logs will be kept about the types of supports that you received, and any challenges of facilitators experienced.

Wellness Hub Data Collection Activities, including:

1. **Completing a LTCH/RH Questionnaire**. LTCH/RH leadership or the designated LTCH/RH 'point person/people' will be asked to complete a LTCH/RH Questionnaire designed to collect information about the LTCH/RH, such as the age of the building, type of LTCH/RH, number of residents, number of staff (including those trained in IPAC), heating ventilation and air conditioning (HVAC) and air exchange, and number of 4-bed rooms.

2. **Completing a needs assessment interview**. If you consent to participate in the program, we will ask 1-3 staff members at the LTCH/RH to participate in an interview to discuss the most pressing challenges and needs you are experiencing at the LTCH/RH (option to include more individuals if deemed appropriate). The objective of this interview is 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. Potential participants will be provided with more information about these components when they are recruited and will be informed that participation is completely optional.

3. Additionally, the research project focused on better understanding COVID-19 spread in LTCH and RH settings will be implemented at all 72 participating sites. If you are participating, the LTCH/RH staff, staff's household members, residents, and residents' caregivers will be approached to participate in some of the following data collection activities (depending on eligibility):
    a. Provide dried blood spot sample (now and at a follow-up time point, if applicable).
    b. Complete a demographic questionnaire (now and at a follow-up time point, if applicable).
    c. Linking their study data to their OHIP card.
    d. Potential opportunity to participate in other studies about correlates of protection against COVID-19.

    We will coordinate with your site to recruit these individuals, however we will lead the recruitment and data collection process. Potential participants will be provided with more information about these components when they are recruited and will be informed that participation is completely optional.

    We will also use some of this data to assess the impact of the Wellness Hub Program and adjust the program according to your needs.

Potential Risks (Injury, discomfort and inconvenience)

- *Risk:* There is potential for a privacy breach where any identifiable study data outlining LTCH/RH challenges including adherence to IPAC best practices is made public.
    - *Measures taken to reduce risk:* The study team is using rigorous strategies to maintain privacy and confidentiality throughout the project (see below). Identifying information will be removed from all written reports and presentations to protect sites' privacy. You can withdraw from this study at any time without further consequences or limitations. The project team is available to discuss your concerns and/or refer you to appropriate resources.

Potential Benefits

Participation in this research study will provide you/your LTCH/RH with additional resources that may support the execution of wellness or IPAC best practices and the uptake of vaccine confidence and wraparound care support resources for staff. This may improve COVID-19 preparation and management in your LTCH/RH.

Privacy and Confidentiality of Your Personally Identifying Information and Study Data (i.e., LTCH/RH questionnaire and Wellness Hub Program Supports 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 will be identified by a site 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 (if applicable) 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.

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.

Withdrawal from the Study

- If you choose to have your LTCH/RH site take part in this study, you can change your mind without giving a reason, and you may withdraw your LTCH/RH site from the study at any time without any negative effects. Generally, if you withdraw your site this will terminate any LTCH/RH -level activities being provided through the program (e.g., saliva testing, facilitated support access if applicable). Any individuals at your site who consented to participate in the study sub-components would remain in the study unless they indicate that they would like to withdraw. However, the specifics around how this may affect the ongoing research project focused on COVID-19 spread in LTCHs and RHs may be tailored to the specifics of your site (e.g., resources, willingness to have facilitators come on site still).
- If at any time you want to withdraw from this study, please contact a member of the study team. Any data collected about the support program and or through LTCH/RH questionnaire 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.

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.

Participation in the Study
Your participation in this study is voluntary. If you choose not to participate, there will be no impact to the medical care received, employment at, or other relationship with Unity Health now or in the future for you and your family or from your LTCH/RH.

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.