CLINICAL TRIALS ONTARIO

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Informed Consent Form for Participation in a Research Study

Study Title: Effect of a Navigator Program on Post-Hospital Outcomes for Homeless Adults: A Pragmatic Randomized Controlled Trial

Principal Investigator: Dr. Stephen Hwang, MD MPH, Centre for Urban Health Solutions, St. Michael's Hospital, 416-864-5991(M-F, 9 AM – 5 PM)

Funder: The Navigator program is funded by the St. Michael's Hospital Foundation and this research study is funded by a CIHR Foundation Grant

INTRODUCTION

You are being asked to consider participating in this research study because you are experiencing homelessness and have been admitted to St. Michael's Hospital. All research is voluntary – you do not have to participate, and you can withdraw at any time. Before agreeing to take part in this research study, it is important that you read the information in this 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, ask the study doctor ot study staff. You should also be aware that it is possible that the St. Michael's Hospital Principal Investigator may also be your treating doctor.

If you choose to participate in the study, you will need to sign this Letter of Information and Consent Form. You should not sign this form until you are sure you understand the information. You may also wish to discuss the study with others, such as your case manager, family doctor, a family member, or close friend.

IS THERE A CONFLICT OF INTEREST?

The study doctors and study staff do not have any conflicts of interest, financial or otherwise, related to this study or its outcome.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

Individuals experiencing homelessness often face significant challenges accessing important healthcare services and social supports during and after hospitalization. The Navigator program – a unique case management program - seeks to help participants follow their post-discharge plans, address their specific needs, and connect with community-based health and social services. This study will examine health, healthcare and social service use, and quality of care transition over 180-days after hospital discharge.

The care that you will receive in the hospital will not be changed if you decide to participate in this study. All research interventions and activities will be in addition to usual care. Usual care consists of support during your hospital stay from care transition facilitators and/or social workers. All participants will also receive counselling from their care team and will be provided with a written discharge summary and/or prescription as needed.

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WHY IS THIS STUDY BEING DONE?

The purpose of this study is to examine if the Navigator program improves post-hospital outcomes for individuals experiencing homelessness. Findings from this research will be used to design new programs to improve care and post-hospital outcomes for individuals experiencing homelessness.

WHAT OTHER CHOICES ARE THERE?

You do not need to participate in this study to receive usual care from your care team, care transition facilitators, and/or social workers. However, please note that access to the Navigator program is limited to only those that participate in this study and are assigned to the Navigator program group.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about 640 people will take part in this study, with 320 participants receiving the Navigator program and 320 receiving usual care.

This study should take 2 years to complete, and the results should be known in about 2.5 years.

WHAT WILL HAPPEN DURING THIS STUDY?

This is a randomized, controlled, and unblinded study. Randomized means you will be put into a group by chance, like flipping a coin. A computer program will place you into one of two study groups after the baseline interview. Your answers to the baseline interview will NOT determine which group you are placed in and the interviewer is NOT able to decide or influence which group you are placed in. You will have an equal 1 in 2 chance of being placed in one of two study groups. Group 1 includes those receiving the Navigator program and Group 2 includes those receiving usual care. This study is controlled because it includes a comparison group (Group 2), which is the usual care group that will receive the current standard of care. Unblinded means that you and your care team will know to which group you have been assigned.

WHAT IS THE STUDY INTERVENTION?

Participants in Group 1 will be assigned to a Homeless Outreach Counsellor. Participants in Group 2 will not be assigned to a Homeless Outreach Counsellor. The Homeless Outreach Counsellor will meet participants in the hospital and work with them for up to 90-days post-discharge. Services from the Homeless Outreach Counsellors will depend on the specific needs of the participants. The broad goals of the Navigator program are to link participants with resources in the community, support participants with their post-discharge plans, and help them meet their specific needs.

WHAT ARE THE STUDY PROCEDURES?

INTERVIEWS

If you consent to participate in the study, you will be asked to do a total of 2 interviews: one after you have enrolled in the study and another 30-days after your hospital discharge. The interviews will take approximately 30-45 minutes to complete. During the interviews, we will ask you a series of questions. We will collect basic information about you, your healthcare use, social service use, health status, medication adherence, care transition, and basic needs. You can skip questions that you do not wish to answer.

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Trained research assistants will be conducting the interviews. The baseline interview may take place over the phone or in-person during your current hospitalization. The 30-day interview may take place over the phone or in-person at a location that is convenient for you.

We will ask you to provide contact information so we can reach you after your hospital discharge regarding the 30-day interview. This contact information may include your phone number and e-mail. We will also ask you to provide contact information for your friends, family members, or other agency contacts.

We will ask you to contact the research team 2-3 weeks after you are discharged from the hospital to schedule your 30-day interview.

COLLECTING HEALTH-RELATED DATA FOR RESEARCH USE

If you agree to participate in this study, the study staff will collect the following information from your medical records at Unity Health Toronto (St. Michael's Hospital): basic information about you and information about your current hospitalization. . With your permission, we will also contact your primary care provider and other healthcare providers about your appointments after hospital discharge.

For participants in the Navigator program group, we will also collect information from your Homeless Outreach Counsellor about the number and nature of interactions that your Homeless Outreach Counsellor have with you, healthcare providers, and social services.

ICES DATA LINKAGE

We also ask for your permission to securely send your study data to ICES to be linked to information collected about your healthcare service use in Ontario. We will only be looking at what kinds of healthcare services you use and how often you use these services prior to enrollment in the study and after you have been discharged from the hospital . This will be done by linking your study data using your name, date of birth, and Ontario health card number to databases held at ICES. ICES is an independent and non-profit organization, whose core purpose is to conduct research that contributes to the effectiveness, quality, equity, and efficiency of healthcare and health services in Ontario. The ICES databases store information about physicians, hospitals, home care services, and medications that are paid for by the Ontario Health Insurance Plan (OHIP). This additional information will help us understand and measure the impact of the Navigator program on healthcare service use.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

The study intervention will last throughout your hospital stay and for about 90 days after hospital discharge.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

Your participation in this study is completely 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.

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You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the study doctor or study staff. The study staff 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 withdraw from the study, no more data about you will be collected. The information you have provided us up until the time that you leave the study will still be kept for research purposes, unless you give us specific instructions to discard your data.

CAN PARTICIPATION IN THIS STUDY END EARLY?

The study doctor may stop your participation in the study early, and without your consent, for reasons such as:

- If continuation in the study appears to be harmful to you
- If it is discovered that you do not meet the eligibility requirements

If you are removed from this study, the study doctor will discuss the reasons with you.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

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 you would like to talk to the study staff, someone from your care team, or someone outside of St. Michael's Hospital for support after the interview, please let us know and we will help you to do that.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

Participants receiving the Navigator program may benefit from the case management service.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

This section describes how your personally identifying information and study data will be accessed, disclosed, and stored during this study. Personally identifying information is any information that could be used to identify you and includes your name and date of birth. Study data is information that is generated by and/or collected for a study that has been stripped of personally identifying information.

All persons involved in study will make every effort to keep your personally identifying information private and confidential in accordance with all applicable privacy legislation, including the Personal Health Information Protection Act (PHIPA) of Ontario. This information will only be used to get in touch with you and access your health records with your consent. All study data collected for research purposes will be labelled with a unique study identification number instead of your personally identifying information. The Survey Research Unit at St. Michael's Hospital is in control of the key that links your study identification number to you personally and will keep it stored separately from the study data. No personally identifying information will be allowed off site in any form, unless required by law. Other than the study team or groups described in this section, no persons will have access to your personally identifiable information without your consent, unless required by law. In addition to the

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study personnel, other employees of Unity Health Toronto may have access to your personally identifying information so that they can carry out regulatory or institutionally required duties.

Accessing and Collecting Information from Your Unity Health Toronto Medical Record
By signing this form, you are authorizing access to your medical records by the study team. The study team will also collect information from your medical record. The information that will be collected is described in the Study Procedures section. The study team will use this information to conduct the study.

You are also authorizing access to your medical records by representatives of the Unity Health Toronto Research Ethics Board. Such access will only be used to verify the authenticity and accuracy of the information collected for the study, without violating your confidentiality, to the extent permitted by applicable laws and regulations.

Accessing and Collecting Information from Providers
By signing this form, you are giving us permission to contact your healthcare providers. These providers may ask you to give separate consent to allow them to release your medical information to us. The information that will be collected from other institutions or providers is described in the Study Procedures section. The study personnel will use this information to conduct the study.

Linking to ICES
Personally identifying information will be securely transferred from St. Michael's Hospital by the study investigators to ICES so the required links can be made to collect study data. The information that will be sent is described in the Study Procedures section.

USE OF EMAIL/TEXTING FOR RESEARCH
There are common risks of using email and/or texting 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 and/or texts they may know that you are a participant in this study or see any health information included in the email and/or text.
- Emails and/or texts may be read or saved by your internet or phone provider (i.e. Rogers, your workplace, and "free internet" providers).
- Copies of an email and/or text may continue to exist, even after efforts to delete the email and/or text have been made.
- There is always a chance with any unencrypted email and/or text, however remote, that it could be intercepted or manipulated.

Do not use email and/or text messaging for medical emergencies. If you require immediate help, call your clinic or care provider, or seek emergency services.

PERSONALLY IDENTIFYING INFORMATION AND STUDY DATA STORAGE
All data used in this study will be securely stored. At each interview, responses will be collected electronically using SNAP Professional Software. This platform has been reviewed and approved for use by St. Michael's Hospital. All electronic data will be kept on a secure server in an unreadable format for anyone outside of the study. Study data may be transferred outside of Unity Health Toronto and may be

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shared with others for purposes related to the conduct of this research study. Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the Unity Health Toronto Research Ethics Board.

PERSONALLY IDENTIFYING INFORMATION RETENTION

Personally identifying information collected for research purposes will be kept by the Principal Investigator and Unity Health Toronto for as long as required by Unity Health Toronto policy (currently 7 years after the study ends), at which point any documents with personally identifying information will be destroyed.

We may wish to contact you in the next 3 years regarding additional research related to this study. You are under no obligation to participate in additional research. At the end of this consent form you can let us know if you give permission for us to contact you again. If you do not want to be contacted about future research, the list connecting your personal information (such as your name and address) to your unique study identification number will be destroyed upon completion of analysis. If you do consent to be contacted about future research, we will keep this information until the end of the 3-year period. All other electronic files will be deleted, and consent forms will be destroyed 7 years after the end of the study.

STUDY DATA RETENTION

As a reminder, study data is information that is generated by or collected for a study that has been stripped of personally identifying information. Study data may be kept indefinitely and may be used for other research or analyses by the investigators. However, the results of any research from this study will include information from many people grouped together so that no one person can be identified. No records of personal information that could be linked to you will ever be reported. The Principal Investigator will protect your records and keep all your information confidential to the greatest extent possible by law.

WILL FAMILY DOCTORS/HEALTH CARE PROVIDERS KNOW WHO IS PARTICIPATING IN THIS STUDY?

On the signature page of this consent form, you will be asked to consent to allow the study team to contact your family doctor and healthcare providers about your appointments after your hospitalization.

WILL INFORMATION ABOUT THIS STUDY BE AVAILABLE ONLINE?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. You may also contact the Principal Investigator after the study is completed to access and discuss results.

WHAT IS THE COST TO PARTICIPANTS?

Participation in this study will not involve any direct additional costs to you. If you need to travel to and from the 30-day interview, you will also be reimbursed for the cost of round-trip public transportation fare.

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ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

If you agree to participate in the study, you will be provided with honorariums after each interview to compensate you for your time. After the baseline interview, you will be provided with a $20 Tim Horton's gift card or another type of gift card such as a Presto gift card or a grocery gift card for the same amount, if requested. After the 30-day interview, you will be provided with $40 by cash, e-transfer, or cheque. Honorariums after each completed interview will be provided to you whether or not you complete the entire study. If you contact the research team 2-3 weeks after you are discharged from the hospital to schedule your 30-day interview, you will be provided with an additional $10, and will receive this at the 30-day interview, for a total of $50. If you do not contact the research team to schedule the interview, we will contact you and you will not receive the additional $10. All participants who complete the 30-day interview will receive the same $40 compensation for their time.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study. You have the right to be informed of the results of this study once the entire study is complete.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. By signing this form, you do not give up any of your legal rights against the study doctor or involved institutions for compensation, nor does this form relieve the study doctor or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If at any time during the study you have questions about the study or the research activities, you should contact the Principal Investigator, Dr. Stephen Hwang, at 416-864-5991(M-F, 9 AM-5PM), or contact the Research Coordinator, Rebecca Brown, at 416-864-6060 ext. 77492 (M-F, 9 AM-5PM).

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).

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Signature Pages: Documentation of Informed Consent

EFFECT OF A NAVIGATOR PROGRAM ON POST-HOSPITAL OUTCOMES FOR HOMELESS ADULTS: A PRAGMATIC RANDOMIZED CONTROLLED TRIAL

Participant Statement of Consent

By signing this consent form, I acknowledge that:

- This research study has been explained to me, and my questions have been answered to my satisfaction.
- I have been given sufficient time to read and understand the information in this consent form.
- I have been informed of the alternatives to participation in this study.
- I know that I have the right not to participate and the right to withdraw from this study without affecting the medical care received, employment at, or other relationship with Unity Health now or in the future for me or my family.
- The potential risks and benefits (if any) 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 will be given a signed and dated copy of this consent form.

I consent to participate in this study.

Participant Name (Print)	Participant Signature	Date	Time

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	Time

Liu M, *et al. BMJ Open* 2022; 12:e065688. doi: 10.1136/bmjopen-2022-065688

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Consent for Telephone Completion (Research Staff Only)

I have explained to the participant the nature, purpose, potential benefits, and possible risks associated with participation in this research database. I confirm that the information in the letter of information and any other written information was accurately explained to, and apparently understood by, the participant. I have answered all questions that have been raised.

I will send a copy of the letter of information to the participant for his/her records.

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

Consent signed for:		on	
	Name of Participant		Date

Letter of Information sent by:		on	
	Name of Participant		Date

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CONSENT TO CONTACT HEALTHCARE PROVIDERS

I consent to the study staff contacting my primary care provider and other healthcare providers regarding my appointments for the purpose of this study.

☐ Yes _____ (initials) ☐ Declined

CONSENT TO REVIEW MEDICAL RECORDS AT ST. MICHAEL'S HOSPITAL

I consent to the study staff reviewing my medical records at St. Michael's Hospital regarding my medical and hospitalization history for the purpose of this study.

☐ Yes _____ (initials) ☐ Declined

CONSENT TO THE RELEASE OF INFORMATION BY CONTACT PERSONS

I consent to the study staff contacting the individuals I have listed as alternate contacts (who have agreed to be contacted if needed), organizations, and agencies that I use when attempting to contact me for the purpose of conducting the 30-day follow-up interview. I agree to allow the study staff to link my name, gender, date of birth, and health card number to obtain information from these agencies. I authorize these people to release information regarding my up-to-date mailing address and phone number to the study staff.

☐ Yes _____ (initials) ☐ Declined

CONSENT TO THE RELEASE OF HEALTH RECORD INFORMATION BY THE HOMELESS OUTREACH COUNSELLORS

I consent to the study staff accessing my Homeless Outreach Counsellor case notes for the purpose of this study.

☐ Yes _____ (initials) ☐ Declined

CONSENT TO THE RELEASE OF HEALTHCARE USE INFORMATION FOR ICES DATA LINKAGE

I consent to the study staff linking my provincial health card number, my name, sex, and date of birth to Ministry of Health files to obtain information about my use of healthcare services for the past three years and for the next year.

☐ Yes _____ (initials) ☐ Declined

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Consent to be Contacted in the Future for Research Purposes

We would also like to ask that you consider providing consent to be contacted about future research studies. The information that you should consider before agreeing to this is outlined below.

The study staff may wish to contact you in the next 3 years regarding additional research related to this study and the Navigator program. Study staff may contact you through phone or e-mail. Your contact information will be stored in the Master Linking Log that will be kept separately from the study data by the Survey Research Unit at St. Michael's Hospital. This data will be stored on a secure server in a password protected file. Only members of the study staff who are not connected to any part of your care will have access to your contact information.

You are not obligated to participate in any research studies that you are contacted about. If you no longer want to be contacted about future research studies, please contact the research coordinator, Rebecca Brown, at 416-864-6060 ext. 77492 (M-F, 9 AM-5PM).

STATEMENT OF CONSENT TO BE CONTACTED IN THE FUTURE FOR RESEARCH PURPOSES

	I agree to be contacted by **email**. Email address: _____ **Please note that email is not secure. Emails can be intercepted, viewed, changed, or saved by others*
	I agree to be contacted by **telephone/text**. Telephone Number: _____
	I agree that the study staff can **leave a voicemail or message** if I do not answer the telephone.

I have read the above information, and I agree to be contacted for future research as indicated above.

Participant Name (Print)	Participant Signature	Date

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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 study staff obtaining consent.

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

Contact Information of Interpreter: _____

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