Informed Consent Form for Participation in a Research Study

Study Title: Addressing Child and Family Social Determinants of Health Needs with Social Navigation: Navigating Social Resources for Children's Health "NSRCH" Clinic

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INTRODUCTION

As a Substitute Decision Maker, you are being asked to provide informed consent on behalf of a person who is unable to provide consent for him/herself. If the participant gains the capacity to consent for him/herself, your consent for them will end. Throughout this form, "you" means you or your child. We encourage parents to include their child in the discussion and decision making to the extent that the child is able to understand.

You are invited to participate in this study because you have been diagnosed with diabetes mellitus type 1 (T1D) or type 2 (T2D), are attending CHEO's Diabetes Clinic and have screened positive on the social determinants of health screening questionnaire. Before agreeing to take part in this study, it is important that you read and understand this document. This consent form provides you with information to help you make an informed choice. Please ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision. You may find it helpful to discuss it with your friends and family.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. Deciding not to take part or deciding to leave the study later will not affect the care you receive at CHEO.

IS THERE A CONFLICT OF INTEREST?

The CHEO Research Institute is receiving financial payment from the Funders to cover the cost of conducting this study.

The study doctors and study staff have no other conflicts of interest related to this study.

WHY IS THIS STUDY BEING DONE?

CHEO's vision is "The best life for every child and youth". In order to implement this vision, it is important to understand the social and economic context in which children and youth live; this is called their social determinants of health. Although this is well recognized, many health care providers do not address social determinants of health because of the lack of easily accessible resources once social needs are identified.

The current standard or usual care in the diabetes clinics at CHEO is to refer families to a social worker once a social need has been identified. Social workers have the ability to support families once social needs are identified. However, there are limited social worker resources available in the diabetes clinic and it can be challenging for them to meet the needs of all the families requiring support.

We are implementing a new way for families to receive the support they need using social navigators. Social navigators are individuals who have been specifically trained to provide support to families with identified social needs. They have been used in community settings, like family doctors' offices, but have not been tested in an outpatient clinic setting at CHEO. Our goal is to support families with identified social needs with timely access to appropriate supports and resources using a social navigator.

WHAT OTHER CHOICES ARE THERE?

You do not have to take part in this study in order to receive treatment or care. If you choose not to participate in this study you will receive standard care as usual in the diabetes clinic, which may include a clinical referral to the diabetes social worker.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about 104 participants will take part in this study, from the CHEO diabetes clinics.

This study should take approximately 2 years to complete and the results should be known about 6-12 months after the study is done.

WHAT WILL HAPPEN DURING THIS STUDY?

If you consent to participate in this phase of the study, your involvement will include:

1. Assignment to a group

If you decide to participate then you will be "randomized" into one of the groups described below. Randomization means that you are put into a group by chance (like flipping a coin). There is no way to predict which group you will be assigned to. You will have an equal chance of being placed in either group. Neither you, the study staff, nor the study doctors can choose what group you will be in. The group options are:

Social navigator group (experimental intervention):

If you are randomized to this group you will be referred to the social navigator for support in accessing resources identified in your screening questionnaire. The social navigator is a member of the study team who has been specifically trained to provide support to families who have identified social needs.

Social worker group (non-intervention group):

If you are randomized to this group you will receive routine clinical care as usual, which will involve a referral to the clinic social workers.

2. Non-Experimental Procedures

The following tests will be done as part of your routine clinical care, and the clinical results will be collected for the purpose of the study. Some of these may be done more often than if you were not taking part in this study:

- Diabetes clinic visits with your regular diabetes doctor
- Hemoglobin A1c: we will collect the results of your routine clinical bloodwork to use for the study. We will ask that your hemoglobin A1c is done when you enter the study, and at the end of the study
- If you are randomized to the social worker group, you will have appointments with the clinic social worker and information from these appointments, such as the number of appointments you attend and the number of resources you access, will be collected for the study.

3. Experimental Procedures

Social navigator appointments:

If you are randomized to the social navigator group, you will attend appointments with the study social navigator, who will support you in accessing any resources you may need. Information from these appointments, such as the number of appointments you attend and the number of resources you access, will be collected for the study.

Questionnaires:

You and your family/caregivers will be asked to complete a series of questionnaires at baseline and at the end of the study 6 months later. Questionnaires will be completed during your scheduled social navigator or social worker appointments. The questionnaires are for participants who are in both groups (the social navigator and the social worker groups).

The information you provide on these questionnaires is for research purposes only, which means that the results will not be reviewed by your health care team. If you wish them to know this information please bring it to their attention.

The questionnaires will cover topics such as quality of life and your satisfaction with the services you received. In total, the questionnaires will take about 15-30 minutes to complete.

Optional Demographic Information

During the study, we will ask you some optional questions about your family structure, parental education level, household income, housing, ethnicity, and preferred language. This information will help us to better understand how we can best support you. We will also use this information to help describe who has participated in our study. Providing us with this information is **optional** and will not affect your participation in the study or the care you receive at CHEO. This information is also **confidential**, meaning that we will not share this information with anyone, and you get to decide who (if anyone) outside the study team knows about this information.

4. Access to Health Information

We will access your medical records to collect information about you that has already been recorded in your medical chart from your previous visits to CHEO, such as date of diabetes diagnosis, medication/ insulin regimen, use of continuous glucose monitoring, other chronic illnesses, previous visits with social workers, and any other information that is relevant to the study.

We will also collect information from your medical record and social worker or social navigator documentation on an ongoing basis once you enroll in the study. This information will include the number and description of appointments with the social worker or social navigator, the resources you were referred to, the resources you accessed, and other information relevant to the study outcomes.

DATA STORAGE:

Your clinical data is stored in your patient chart at CHEO in a system called Epic. Your research data will be stored in a data platform called REDCap. REDCap, which stands for Research Electronic Data Capture, is a secure database on the CHEO server. The data will be maintained by CHEO and can only be accessed by people who are involved in the research.

To protect your identity, your study information will be coded, which means that no directly identifying information about you, such as your name or address, will be in your study records. Despite protections being in place, there is a small risk of unintentional release of information.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to participate in this study, you will be expected to:

- Tell the study staff about your current medical conditions;
- Tell the study staff about your current diabetes treatment regimen and about any other medications you are currently taking;
- Attend all study visits and complete all study related questionnaires;
- Ask your study team about anything that worries you;
- Tell study staff anything about your health that has changed;
- Tell the study staff if you change your mind about being in the study.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

Your participation in this study will last approximately 6 months. You will be asked to complete questionnaires at baseline (first study visit) and again 6 months later. You will also be asked to attend appointments with your social worker or social navigator and the number of appointments will depend on your needs and availability.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

It is your choice to take part in this study, participation is voluntary. You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. The study team may ask why you are withdrawing for reporting purposes, but you do not need to give a reason to withdraw from the study if you do not want to. Withdrawal from the study will not have any effect on the care you or your family will receive at CHEO. If you decide to leave the study, you can contact the study doctor or a member of the study team to let them know.

You may withdraw your permission to use information that was collected about you for this study at any time by letting the study doctor know. However, this would also mean that you withdraw from the study.

CAN PARTICIPATION IN THIS STUDY END EARLY?

Your participation on the study may be stopped early, and without your consent, for reasons such as:

- The research team decides to stop the study;
- The research ethics board withdraw permission for this study to continue;
- The study doctor thinks it would be in your best interest not to continue in the study.

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

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

Potential emotional/psychological risks: Some of the questionnaires contain questions about personal topics and make you feel embarrassed. You can choose to skip any questions that make you feel this way.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

If you decide to participate, it is unlikely that you will benefit directly from this study, since we are hoping to show that the social navigator provides support just as well as the social workers. While we cannot know this for sure, we hope the information learned from this study will help other people with diabetes in the future.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the study doctors and study staff will only collect the information they need for this study.

Records identifying you at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- This CHEO Research Institute, who oversees the conduct of research at this location.
- The Children's Hospital of Eastern Ontario Research Ethics Board, who oversees the ethical conduct of this study at this location.

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your participant code, sex, and date of birth.

Any information that may indicate that a child is being harmed or at risk of harm would not be kept confidential and instead be disclosed to appropriate authorities.

The use of virtual platforms, like any internet communication or storage and retention of information, involve privacy risks around access and disclosure of information, however, there are safeguards in place to reduce these risks, (e.g., account registration, meeting passwords, disposal of records or devices on which information is stored).

This research study is collecting information on sociodemographics and ethnicity as well as other characteristics of individuals because these characteristics may influence which supports people need or how people respond to different interventions. Providing this information is voluntary and will not affect your participation in this study or the care you receive at CHEO.

We plan to communicate with you using email and/or text messages throughout the study. We will be contacting you for scheduling study visits, reminding you to attend the visits, and links and reminders about the study questionnaires. Communication via e-mail and text message is not absolutely secure. We do not recommend that you communicate sensitive personal

information via e-mail or text message.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/ presented to the scientific community at meetings and in journals. We will keep the study data for 7 years after the results are published.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

A copy of the consent form that you sign to enter the study will not be included in your health record/hospital chart.

Other future research

Your coded study data may be used or shared with other researchers (inside and outside of Canada) for future studies. “Coded” means that directly identifying information (such as your name and date of birth) will be replaced by a randomly generated number, which will be applied to the study data. This may include storing the coded study data samples in controlled-access databases, for which access is limited to researcher(s) who submit a study plan and who sign an agreement to use the coded study data and/or coded samples only for that research. Very limited coded study data may also be placed in an open access, publicly accessible database. The goal of sharing is to make more research possible. However, the code matching your study data with your name and other directly identifying study data will not be shared.

You will not be asked if you agree to take part in future research studies using your study data. You or your study doctor will not be told what type of research will be done. You will not be given reports or other information about any research that is done with your study data.

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

Your family doctor/health care provider will not be informed by the study team that you are taking part in the study. You can choose to let your family doctor/health care provider know, if you like.

WILL INFORMATION ABOUT THIS STUDY BE AVAILABLE ONLINE?

A description of this clinical trial will be available on www.clinicaltrials.gov. This website will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

WHAT IS THE COST TO PARTICIPANTS?

Participation in this study will not involve any additional costs to you or your private health care insurance.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

If you decide to participate in this study, transportation costs (i.e., parking) will be provided for required in-person study visits. You will also receive a $25 Amazon gift card.

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 your involvement in the study. All results will be reported back to you by your study doctor.

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 you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to your study doctor. That person is:

Dr. Caroline Zuijdwijk	613-737-7600 ext. 4156
Name	Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. That person is:

CHEO Research Ethics Board	613-737-7600 ext. 3272
Name	Telephone

SIGNATURES

- All of my questions have been answered,
- I understand the information within this informed consent form,
- I allow access to medical records and related personal health information as explained in this consent form,
- I do not give up any legal rights by signing this consent form,
- I agree, or agree to allow the person I am responsible for, to take part in this study.

_____	_____	_____
Signature of Participant/ Substitute Decision-Maker	PRINTED NAME	Date

If consent is provided by Substitute Decision Maker: _____ PRINTED NAME of Participant

_____	_____	_____
Signature of Person Conducting the Consent Discussion	PRINTED NAME & ROLE	Date

The following attestation must be provided if the participant is unable to read or requires an oral translation:

If the participant is assisted during the consent process, please check the relevant box and complete the signature space below:

☐ The person signing below acted as an interpreter, and attests that the study as set out in the consent form was accurately sight translated and/or interpreted, and that interpretation was provided on questions, responses and additional discussion arising from this process.

_____	_____	_____
PRINT NAME of Interpreter	Signature	Date

_____
Language

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to the participant, and any questions have been answered.

_____	_____	_____
PRINT NAME of witness	Signature	Date

_____
Relationship to Participant