CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Implementing & Evaluating a Rehabilitation Research Volunteer Pool (RVP) at Toronto Rehabilitation Institute

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Introduction:

You are being asked to take part in a research study. Please read the information about the study presented in this form. This form describes the risks and benefits of study enrollment, the information you should know before you decide to take part. Before you make your decision, feel free to talk about the research volunteer pool with anyone you wish, including your friends, family, and healthcare team. Take as much time as you need to make your decision. You should ask the research staff to explain anything in this form that is unclear to you, or you do not understand. Please make sure all of your questions have been answered before signing this consent form. Participation in this study is voluntary.

Background:

At Toronto Rehabilitation Institute (TRI), scientists want to enroll eligible and interested participants in their studies, but struggle to locate volunteers who meet their eligibility criteria. Patients and former patients want to get involved in research but sometimes find it difficult to figure out how to volunteer to do so.

Purpose:

We propose to develop, implement, and evaluate a Research Volunteer Pool (RVP) database for TRI. The RVP is an online database containing contact and demographic information provided by each RVP member, as well as some health history information. This information will be used to screen members for eligibility for various research studies being conducted at TRI.

The primary aim of this study is to facilitate the universal and equitable introduction to research and access to the research volunteer pool (RVP) to Toronto Rehabilitation Institute (inpatients and outpatients) and to allow scientists access to RVP members. This will be measured in terms of the number of people who enroll in the RVP, the number of members who are

contacted by researchers to be screened for enrollment, and in the number of members who consent to studies over the term of their membership.

The secondary measures will include insights about RVP members, their impairments and rehabilitation treatment histories, and the number of TRI scientists who use the RVP. These findings will inform future research design at TRI.

Study Design:

This is an observational study about research volunteerism in the inpatient and outpatient rehabilitation setting using a new database to assist researchers in recruiting 1) volunteers for research studies, and 2) research partners. This is a voluntary database. You are signing up to be on a list of people who can be contacted by TRI researchers to see if you want to participate in research as a participant or a research partner. A research partner may include being asked for research ideas, providing your feedback regarding study procedures, assist with analysis and interpretation of research findings, and assist in the sharing of results with members of the public. RVP members who consent to being approached about being a research partner, will be asked as the need for research partners arise.

Enrolment in the database is open to current or former patients of TRI who want to share information about themselves with TRI researchers.

Study Procedures:

To become a member of the RVP, there are several ways to do so such as in person, on the website, or by telephone:

- If you are an inpatient at TRI you will meet with a research staff member, called a Patient Research Liaison (PRL), who will introduce you to the RVP and review this consent document.
- Current or former patients can register themselves online by following the instructions provided on the website (https://www.kite-uhn.com/service/central-recruitment)This consent form is available online for you to read and agree to if you choose.
- You can call the RVP Office at 416-597-3422 x7809, a staff member will read this consent form to you and you can provide verbal consent over the phone.

Once you consent to become an RVP member, you will be provided with a link by email to access the RVP portal and enter your contact information which will generate an RVP member ID#. If you do not have an email address, they can assist you in entering your contact information over the phone or in person.

You will need to provide some general information about yourself, such as your age, and education on a Demographics form, as well as your contact information. There are ten additional sections about your health. These forms will take about 10-30 minutes to complete and are optional. We ask you to complete these pages so we can match you to active research studies. The forms are titled as follows:

- *Patient History*
- *Lifestyle*
- *Mobility*
- *Exercise*
- *Caregiving*
- *Health Conditions*
- *Trouble with Daily Activities Questionnaire*
- *Health Utilities Index (HUI)*
- *Work Productivity and Impairment questionnaire (WPAI)*
- *Life Satisfaction Questionnaire (LiSAT-11)*

After you consent, your data will be routinely checked to see if you are eligible to participate in any new studies or other research-related activities. This does not mean you will be enrolled in a study or research activity, just that you may be asked if you would like to get involved or participate. A researcher will contact you, if you may be eligible for a specific study. Details of that specific study will be discussed with you, and you may then decide whether to consent to participate in that study or not. This may happen on more than one occasion and for more than one study. Each time you are contacted it will be up to you to decide to participate or not.

If you select the option of research partner in the RVP, your name will be forwarded to the scientist who oversees these type of research related activities, and you will be contacted as opportunities arise.

Consent for RVP membership will last for five-years. When your consent is nearing expiry, you will be contacted by a RVP staff member and asked if you would like to re-consent for five more years. If you agree, your name will be kept in the RVP database for the extended time period.

Risks:

Taking part in this study has risks. Some of these risks we know about. There is also a possibility of risks that we do not know about. It might be possible that you experience anxiety, distress, embarrassment, or feelings of sadness that may arise from questionnaires. You can skip the section of the questionnaire or questions that will make you uncomfortable. Also, when you complete the questionnaire on the RVP website, there is a very small risk of an internet information leak from the website host. TRI has chosen a reliable website host called EMPOWER that follows best practices and has high standards for privacy and secure data storage; they will take every precaution to prevent this from happening.

Future studies using the RVP to facilitate recruitment of their study sample may have risks, independent of RVP membership. These will be explained to you by the Principal Investigator (PI) of their specific study, before you consent to participate in that study.

Benefits:

You may have direct benefit from being in this study by having regular access to relevant research studies at TRI. Information learned from this study may also benefit Research and

Clinical leadership at TRI, to satisfy both research and clinical goals surrounding patient knowledge and education regarding research, and meaningful participation of patients in rehabilitation research throughout the organization.

Future studies may have benefits independent of RVP membership that will be explained to you by the Principal Investigator (PI) or Study coordinator for their specific study. Please discuss these potential risks and benefits before you consent to participate in the study or research activity.

Alternatives to Being in the Study:

You do not have to join this study; your decision to enroll in the RVP will not affect your current or future care at TRI.

Confidentiality:

If you agree to join this study, the RVP staff and database manager will have access to your personal health information which is provided by you, the member. Personal health information includes your:

- Name
- Partial date of birth (month, year)
- Contact information (address, phone and email)
- Details about your health and function (optional)

The information that is collected for the study will be kept in a confidential database which is encrypted, coded, and password protected. The data in the RVP will be stored for ten years after your last interaction with the database or closure of the database. Only the study team or the people below will be allowed to look at your contact information and completed forms.

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study staff followed proper laws, guidelines and procedures. Representatives of the UHN Research Ethics Board, Database Manager from EmPOWER and the external evaluators of the RVP.

Research Information in Shared Clinical Records

If you participate in this study, information about you from this research project may be stored in your hospital file and in the UHN computer system. The UHN shares the patient information stored on its computers with other hospitals and health care providers in Ontario so they can access the information if it is needed for your clinical care. The study team can tell you what information about you will be stored electronically and may be shared outside of the UHN. If you have any concerns about this, or have any questions, please contact the UHN Privacy Office at 416-340-4800, x6937 (or by email at privacy@uhn.ca).

Any publications or presentations that may come from this study will not identify you directly. The study team can tell you what information about you may be shared outside of UHN.

Voluntary Participation:

Your participation in the RVP is voluntary. You may decide to be in this research database now, and then change your mind later. You may leave the database at any time without having to provide a reason, but you will need to indicate your withdrawal from the RVP online, in person or on the phone so that the study staff are aware.

If you choose not to enroll in the database or decide later to leave the RVP database, your choice will not have any effect on your current or future health care at TRI or UHN.

Withdrawal from the Study:

If you decide to leave the RVP, we will ask if you would like to remove all your data, or just your contact information, before deleting data from the database.

Costs and Reimbursement:

You will not have to pay for any of the procedures or activities involved with the RVP database.

Rights as a Participant:

By signing this form you do not give up any of your legal rights with the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

Conflict of Interest:

The Principal Investigator and her team have an interest in enrolling many people in the database and completing this study. Dr. Craven may have what may be considered a real conflict of interest. She is the Central Recruitment Lead (which includes running the RVP) as well as P.I of other studies at Toronto Rehab that will have access to services of the RVP.

Dr. Craven's role as Lead is to provide oversight to the CR Manager. The CR Manager will provide regular supervision of the CR staff, and interact and collaborate with the UHN Research Ethics Board and RVP members.

All other steering committee members have a similar type of conflict of interest as the CR Lead. These members are the researchers and scientists of the various research studies you might be participating in. Dr. Craven's and other member's interests should not influence your decision to become an RVP member. If you decide not to be an RVP member, it will not affect your current or future care at TRI.

Questions:

If you have any questions, concerns or would like to speak to the study team for any reason, please call Dr. Cathy Craven at (416) 597-3422 ext. 6122 or Louise Brisbois at (416) 597-3422 ext. 6205.

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (UHN REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.

You will be given a signed copy of this consent form.

Consent:

This study has been explained to me and any questions I had have been answered.
I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

Print Study Participant's Name	Signature	Date

My email address :_____

My signature means that I have explained the study to the participant named above and I have answered all questions.

Print Name of Person Obtaining Consent	Signature	Date

For Patients that have a Substitute Decision Maker:
After considering the wishes, values, and goals of the patient I, the Substitute Decision Maker, would permit the study team to perform study procedures and data collection. I can reverse this decision at any time. The study team will review this consent with the patient when their capacity for consent is regained.

Name of Substitute Decision Maker	Signature	Date

Relationship to Participant

Name of Patient

(Continue if applicable)
Was the participant assisted during the consent process? If **YES**, please check the relevant box and complete the signature space below:
☐ **YES** ☐ **NO**

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 them, and any questions have been answered.

Print Name of Witness	Signature	Date

Relationship to Participant