ARC Participant Information and Consent Form

Title of Study: ARC – Access to Resources in the Community/ Accès aux ressources communautaires

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Funding Agencies:
Canadian Institutes of Health Research
SPOR initiative

Participation in this study is entirely voluntary. Please read this Informed Consent Form carefully and feel free to ask the study team or your doctor as many questions as you like to help you decide about participating in this study.

Why am I being given this form?

Your family doctor or nurse practitioner's office is taking part in a study about helping patients make use of resources in the community to help with their health and wellbeing. These resources include exercise or healthy eating classes, programs to help with parenting, sessions to help reduce falls in the elderly, smoking cessation workshops, and many others.

Your family doctor or nurse practitioner has provided you with this information package because he/she has directed you to such a program. This form will explain the study to you, so you can make a decision about if you want to take part in it.

Why is this study being done?

The research team is doing this study to understand how patients can best be supported to use resources in the community that can help them achieve better health and wellbeing. We want to know the type of support that is best suited for people to help them use these programs.

How does the study work?

Patients who agree to participate will be assigned by chance, like the flip of a coin, to one of two types of navigation services. Both types of services aim to help patients find a resource that will provide the care need identified by their provider and that is best suited for the patient. The two types of navigation services are:

Option #1: Participants assigned by chance to this option will receive instructions on how to obtain information on the navigation services offered by a provincial navigation services available to Ontarians.

Option #2: Participants assigned by chance to this option will have access to the services provided by a person working with the research team that is called a Patient Navigator. The Patient Navigator is trained to also help people overcome barriers that can limit their access to the resource they need. This may include helping patients with transportation, language or other things that the patient feels will help them be able to make use of the resource to which they were referred.

We estimate that up to nearly 500 patients will participate in this research study.

What do I have to do?

If you agree to participate in the study:

1. You will be asked to respond to two short surveys; one at the start of your participation and the second one three months later.
2. You will be asked to provide your health care (OHIP) number (optional)

1. **Surveys:** At the start of the study, a member of the study team will call you and ask some questions about yourself, your health and how you manage it, as well as your experiences with the healthcare system. The second survey will repeat some of the questions from the first survey. Asking the same questions before and after your participation helps the researchers determine whether the study has had a benefit to you. The second survey but will also contain questions about your experience with the navigation services to which you were assigned. These questions will help researchers determine how the services may need to be adapted to respond to the needs of the patients.

   Both surveys will be done over the phone and will take about 20-30 minutes to complete You can refuse to answer any question during the surveys.

2. **OHIP number:** The OHIP number You are being asked to provide your health care (OHIP) number, however this is optional. If you agree to share your OHIP number, your study data will be linked to databases held at the Institute for Clinical Evaluative Sciences (ICES) that contain information about the health resources used by Ontarians. If you share your OHIP number, it will be used by the study team to learn about the types of health services that you have used, so they can assess whether the services offered by Ontario 211 or the Patient Navigator influence the types of resources the patient uses. You can still participate in the study regardless of whether you decide to provide your OHIP number or not.

Within two months after completing the second survey, a few patients will be invited to take part in an interview that would allow the researcher team to better understand patients' experience in this research project. If you were to be selected for that part of the study, we would provide more explanation about it at that time, and ask for your consent to participate in that interview.

How long will I be in the study?

The entire study will last 18 months. Your part in the study will last about one to three months.

What are the potential risks I may experience?

There is little risk in taking part in the study.

You might find the surveys to be long or questions to be personal. You might not like all of the questions that you are asked. You do not have to answer any questions that make you uncomfortable.

Can I expect to benefit from participating in this research study?

Taking part in the study may or may not help you. If you take part in this study it may help you find the program in the community that is best suited for you and which you and or your care provider identified as important for you.

By taking part in this study, you will help the study team to determine the type of navigation services that are best suited for patients

Do I have to take part? If I say yes now, can I change my mind later?

You can choose not to participate in this study.

If you choose not to participate, all of the community resources will still be available to you as they are all publicly available.

It is up to you if you take part in this study. Whether you choose to take part, or choose not to, it will not change the care you receive from your family doctor. If you decide to take part in the study and then change your mind later, you may withdraw from the study. At that time, no further information will be

collected from you and you will not be contacted further by the study team, and if you wish, the study team will remove the information you have provided and will not use it in the study.

How is my personal information being protected?

- If you decide to participate in this study, the investigator(s) and study staff will look at your personal health information and collect only the information they need for this study. "Personal health information" is health information about you that could identify you because it includes information such as your name, address, telephone number, date of birth, new and existing medical records, or the types, dates and results of various tests and procedures.
- Information that identifies you will be released only if it is required by law.
- All information collected during your participation in this study will be identified with a unique study number (for example participant # AB01), and will not contain information that identifies you.
- All information and data collected during your participation in this study will be securely stored at the Bruyère Research Institute and Laurentian University.
- If you agree to share your health care (OHIP) number, this will be used by the study team after the study is completed. Your OHIP number will be securely transferred to the Institute of Clinical and Evaluative Sciences (ICES) and will be used to link the survey results to the information that is held at ICES. ICES is an independent not-for-profit corporation. It is known internationally as a trusted, impartial and credible source of high quality health and health services research and evidence.
- Documents leaving the Bruyère Research Institute and Laurentian University will only contain the coded study number.
- A Master List provides the link between your identifying information and the coded study number. This list will only be available to Drs. Dahrouge and Gauthier and their staff and will not leave their respective sites.
- The Master List and coded study records will be stored securely.
- For audit purposes only, your original study and medical records may be reviewed under the supervision of Dr. Dahrouge's and Dr. Gauthier's staff by representatives from:
    - the Ottawa Health Science Network Research Ethics Board (OHSN-REB),
    - the Ottawa Hospital Research Institute
    - the Bruyère Continuing Care Research Ethics Board
    - the University of Ottawa Research Ethics Board
    - the Hôpital Montfort Research Ethics Board
    - Laurentian University Research Ethics Board
    - the University of Ontario Institute of Technology Research Ethics Board
- You will not be identified in any publications or presentations resulting from this study.
- Research records will be kept for 10 years, as required by the OHSN-REB.
- At the end of the storage time, all paper records will be shredded and all electronic records will be securely deleted.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site 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.

This research study can be found on the above listed website by using the clinical trial registration number *[pending approval]*.

Will I be told about any new information that might make me change my mind about taking part in the study?

You will be told as soon as possible if there is anything new during the study that might make you change your mind about taking part in the study. You may be asked to sign a new form.

Who can I call if I have questions?

If you have any questions or should you no longer wish to remain a part of the ARC study, please call Andrea Perna (613) 562-6262 ext.2920 or email arc@bruyere.org. In Sudbury, please call Patrick Timony (705) 675-1151 ext. 4298 or email Pe_Timony@laurentian.ca

You can also contact the study principal investigator, Simone Dahrouge at (613) 562-6262 ext. 2913 or sdahrouge@bruyere.org. In Sudbury, please contact Alain Gauthier at (705) 675-1151 ext. 4301 or email agauthier@laurentian.ca

The Ottawa Health Science Network Research Ethics Board (OHSN-REB), Bruyère Research Ethics Board, the Hôpital Montfort Research Ethics Board, the University of Ottawa Research Ethics Board, the Laurentian University Research Ethics Board and University of Ontario Institute of Technology Research Ethics Board have reviewed this protocol. These Boards consider the ethical aspects of all research studies involving human participants at participating hospitals, institutes and universities.

If you have any questions about your rights as a study participant or about the conduct of this study, please contact:

- Chairperson, OHSN-REB at 613-798-5555, ext. 16719
- Research Ethics Coordinator, Bruyère Research Ethics Board at reb@bruyere.org or 613-562-6262 ext. 4003
- Montfort Hospital Research Ethics Board, 745A suite 102 Montreal road, Ottawa, Ontario at 613-746-4621, ext. 2221 or via email at ethique@montfort.on.ca
- Protocol Officer for Ethics in Research, University of Ottawa, at ethics@uottawa.ca or 613-562-5387
- Research Ethics Officer, Laurentian University at 705-675-1151 ext 3213, 2436 or toll free at 1-800-461-4030 or email ethics@laurentian.ca.
- Ethics and Compliance Officer, University of Ontario Institute of Technology, researchethics@uoit.ca or 905-721-8668 X 3693

Access to Resources in the Community - Accès aux ressources communautaires

Consent to Participate in Research

- I understand that I am being asked to take part in a study called Access to Resources in the Community, or ARC.
- _____ told me about the study.
- I read each page of this form, or had this form read to me.
- All of my questions were answered so that I understand the study.
- I can decide at any time that I do not want to take part in this study anymore.
- I have decided to take part in this study.
- I will get a copy of this signed form.

Optional:

☐ **I agree to have my health card (OHIP) number shared with the study team and ICES.**

My OHIP number is: _____

_____	_____	_____
Participant's Printed Name	Participant Signature	Date

Proxy Consent

Proxy consent is required in the event that the participant is unable to provide informed consent (as identified by the provider in the referral form).

Reason: _____

Proxy Consent Statement

I have explained the information presented in the above consent form to the participant and attest to their understanding of the nature, demands, risks and benefits involved in taking part in this study.

_____	_____	_____
Printed Name	Signature	Date

_____

Relationship with Participant

Investigator or Delegate Statement

☐ **Verbal consent** obtained by _____ _____

Research Assistant Date

I have carefully explained the study to the participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in taking part in this study.

_____	_____	_____
Investigator/Delegate's Printed Name	Investigator/Delegate's Signature	Date