Centre universitaire de santé McGill
McGill University Health Centre

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INFORMED CONSENT FORM

Research Study Title:	Radio-frequency (RF) Bladder Monitor – Pilot Feasibility Test
Protocol number:	2025-10205
Researcher responsible for the research study:	Emily Porter, Research Institute of the McGill University Health Centre, Cancer Research Program Lysanne Campeau, Department of Surgery, Division of Urology, McGill University; McGill University Health Centre
Co-Investigator(s)/sites:	Eleonora Razzicchia, Research Institute of the McGill University Health Centre, Cancer Research Program
Sponsor:	Research Institute of McGill University Health Centre (RI-MUHC)

INTRODUCTION

We are inviting you to take part in this research study because we are looking to recruit adult volunteers for a study on a newly developed medical device for sensing the bladder volume using sensors on the skin. To participate in this study, you must be age 18+, you must have no implantable devices in your body, and you must not be pregnant.

However, before you accept to take part in this study and sign this Informed consent form, please take the time to read, understand and carefully examine the following information. You may also want to discuss this study with your family doctor, a family member or a close friend.

This form may contain words that you do not understand. We invite you to speak to the researcher responsible for this study or to other members of the research team and ask them to explain to you any word or information that is unclear to you before you sign this form.

BACKGROUND

The study aims to test a new device that uses radio-frequency (RF) signals to detect when a person's bladder is full. Over 200 million people around the world experience urinary incontinence (UI), which is common in women, the elderly, people with spinal cord injuries, and those with intellectual disabilities. UI can greatly impact a person's quality of life, independence, and dignity. While there are many causes of UI, this study focuses on people who either can't feel when their bladder is full or can't act on that feeling in time. In these cases, a wearable bladder monitor that gives an alert as the bladder nears fullness could help people avoid accidents and unnecessary medical interventions. This device could support toilet training for children with intellectual disabilities, help prevent accidents in people with spinal cord injuries, and allow elderly individuals in care homes to get to the bathroom on time. Overall, a bladder monitor with early alerts could reduce the negative effects of UI and support independence and well-being.

RF-based technologies could be very useful for supporting UI, as they are safe even for 24/7 use, non-invasive, and low-cost. In this study, we plan to test this bladder monitor with human volunteers for the first time to see how well it works. A small number of healthy volunteers will be recruited so that we can test the real-world feasibility of RF-bladder monitoring and determine how key measurement parameters influence the ability to accurately detect the full bladder.

The word "investigational" means the study device is still being tested in research studies and is not approved by Health Canada for this use.

PURPOSE OF THE RESEARCH STUDY

The purpose of this study is to examine the feasibility of a RF-based device in monitoring the volume of urine in the bladder as it fills and identifying when the bladder is full. We will study how well this technology works in measuring the fullness of the bladder, in humans for the first time.

For this research study, we will recruit up to 10 participants, both men and women, aged 18+.

DESCRIPTION OF THE RESEARCH PROCEDURES

This research study will take place at Research Institute of McGill University Health Centre (MUHC), at 1001 Decarie Blvd, Montreal, Quebec H4A 3J1.

1. Duration and number of visits

Your participation in this research project will include 1 visit, which will last around 2 hours. An additional visit a week or two beforehand may occur to discuss the research study and/or sign the consent form. Participants are invited to participate in the study up to 10 times.

2. Tests and procedures

During your participation in this research study, a member of the research team will conduct the following tests and procedures:

DESCRIPTION OF STUDY PROCEDURES	
Procedure	**Description**
RF data collection	We will collect measurements with the bladder monitor device (up to four sensors will be placed on the skin, on the lower abdomen region, and held in place by sticking a bandage or sticker overtop of them). The amount of time we will collect measurements is estimated to take around 2 hours - Measurements will start with an empty bladder and stop when you feel the urge to go to the bathroom to void your bladder.
Urine collection	When you feel the need to urinate, you will be able to go to the bathroom. You will be asked to collect a urine sample. Your urine sample will be discarded as soon as measurements are recorded, within 12 hours of when you submit the sample to the research staff.
Waist circumference measurement	Using a tape measure, the research will measure your waist circumference.
(Optional) Ultrasound bladder scan	You will be able to opt in to an optional ultrasound bladder scan that is performed at the same time as the measurements with the RF bladder monitor. Ultrasound bladder scans are non-invasive and require placing the ultrasound probe on the skin in the lower pelvic region.

PARTICIPANT'S RESPONSIBILITIES

- Empty your bladder in the restroom prior to commencing the study.
- If you are female, urine will be collected and a urine-based pregnancy test will be used to confirm you are not pregnant. If you are pregnant, you will be withdrawn from the study at this point.
- Have your waist circumference measured by the researcher using a tape measure.
- Have up to six sensors placed on your skin on your lower abdomen in front of the bladder region (i.e., just below the belly button, and above the hip line). You will have to lift up your shirt so that the researcher can place the sensors. Once the sensors are in place you can lower your shirt to cover them.
- Sit or stand while trying to limit your pelvic-region movements as your bladder fills, until you feel the urge to void.

- (Optional): During the bladder filling, also sit or stand still while an ultrasound bladder scan is performed.
- On feeling the need to void, you will indicate this to the researcher and the sensors will be removed.
- Again, use the restroom to void and collect your urine sample in plastic container and return it to the research lab.
- Avoid drinking/eating during the measurements phase of the study.

BENEFITS ASSOCIATED WITH THE RESEARCH STUDY

There is no direct benefit to you for participating in this research. However, we hope that the study results will contribute to the advancement of scientific knowledge in this field and help us find better treatments for patients.

RISKS ASSOCIATED WITH THE RESEARCH STUDY

This bladder monitor is an investigational device, which is still an experimental technology. Therefore, we may not know all the discomforts, side effects and other possible risks associated with it.

Therefore, if you have noticed side effects, whatever they may be, during this research study, you must tell the study doctor immediately, regardless of whether you think these effects are related to the study. Even once your participation in the study is over, do not hesitate to contact the study doctor if you experience a side effect that may be linked to the study.

The lead researcher and members of her team will answer any questions that you may have regarding the risks, discomforts or side effects associated with this study. Also, during the visit, the lead researcher and members of her team will ask you questions about any discomfort you may experience.

1. Risks associated with research procedures

- Exposure to RF waves: There is no known risk associated with low-powered exposure of radiofrequency waves over this frequency range. The power and frequencies used are very similar to those used in cell phones, WIFI, Bluetooth, etc., and the safety of these have been studied extensively. However, some participants may not be comfortable with this type of exposure, as although there are no known or confirmed safety risks at this time, it is possible future studies could show differently.
- Liquids near electrical equipment: As we want participants to wear the sensors through one void-filling-voiding cycle of the bladder, you may want to speed up the process by drinking extra fluids. Participants will be allowed to bring drinks with them and we can provide water. However, since there is a risk therefore of spilling liquids, they will not be able to drink during the measurements themselves. While the risk of spills is most likely in damage to the electrical equipment, in severe cases electrical shocks could also occur if the measurement equipment is immersed. Participants will be separated from the equipment by long cables, elevated equipment, and physical barrier walls. Participants will be asked to drink freely prior to the start

of the measurements, but will avoid eating/drink during the measurements themselves. It may feel uncomfortable not being able to drink for such a duration.

- Loss of Privacy/Confidentiality: Participation in research might involve some loss of privacy. There is small risk that someone outside the research study could see and misuse information about you. More information about how we will protect your information to reduce this risk can be found later in this document.
- Sensor placement on skin: The sensors will be held in place for the duration of the measurement period with bandages or stickers. The bandages have a clip that fastens them around your body; while the stickers are like bandaids with a sticky portion that sticks to your skin, and may cause temporary discomfort or irritation. If you find one type of bandage or sticker uncomfortable, please let the researcher know so they can reposition them or offer an alternate type.

RISKS ASSOCIATED WITH PREGNANCY

Participation in this study may include risks, known or unknown, for pregnant women or unborn children. Consequently, pregnant women cannot take part in this project.

If you are a woman of childbearing potential, you must undergo a pregnancy test before you start participating in the study. This test will take place before performing the RF measurements with the bladder monitor. If you are pregnant, you will be withdrawn from the study at this point. Note that the results of the pregnancy test, and the urine sample collected at this point, are not part of the research of this study and will not be used or reported.

VOLUNTARY PARTICIPATION AND THE RIGHT TO WITHDRAW

Your participation in this research study is voluntary. Therefore, you may refuse to participate. You may also withdraw at any time, without giving any reasons, by informing the doctor in charge of this research or a member of the research team.

Your decision not to participate in the study, or to withdraw from it, will have no impact on the quality of care and services to which you are otherwise entitled, or on your relationship with the teams providing them.

The doctor in charge of this research study, the Research Ethics Board, or the sponsor may put an end to your participation without your consent. This may happen if new findings or information indicate that participation in this research study is no longer in your best interests, if you do not follow study instructions, or if there are administrative reasons to terminate the study.

You have the right to modulate your withdrawal from the study at any time, by

- Stopping your participating at any time,
- Withdrawing from the study completely.

However, before withdrawing from this research project, we suggest discussing the situation with the responsible researcher. If you withdraw or are withdrawn from the study, no further data or samples will be collected. However, the information and the RF data already collected for the study will be stored, analyzed and used to ensure the integrity of the study, as described in this document.

Any new findings acquired during the course of the study that could influence your decision to continue your participation will be shared with you quickly.

CONFIDENTIALITY

During your participation in this study, the doctor in charge of the study and the research team will collect in a study file all of the information and samples about you needed to meet the scientific objectives of the study.

The study file may include: health information from your medical charts including your name, and sex, past and present health status, lifestyle, and

- the results of all tests, exams, and procedures that will be performed.

All these study data collected for this study will remain confidential as described in this Informed Consent Form. You will be identified by a code number only. The key to the code linking your name to your study file will be kept by the doctor in charge of this research study.

The research team will share your coded study data with the sponsor or its representatives. This includes sending your coded health information outside of Québec. The sharing will follow the limits set by the agreement with the sponsor.

Study data will be stored for at least 15 years following the end of the study by the doctor in charge of this research study. Study urine samples will be stored for 12-24 hours by the research team following the end of your participation in the measurements of the study and then discarded.

The study data may be published or shared at scientific meetings; however, it will not be possible to identify you as only de-identified results will be shared.

For monitoring, control, safety, security, and approval of the device by regulatory agencies, your study file as well as your medical charts may be examined by a person mandated by Canadian or international regulatory authorities, such as Health Canada, as well as by authorized representatives of the study sponsor, the institution, or the Research Ethics Board. All these individuals and organizations will have access to your personal data, but they adhere to a confidentiality policy.

You have the right to consult your study file in order to verify the information gathered, and to have it corrected if necessary.

INCIDENTAL FINDINGS

Material incidental findings are findings made in the course of the study that may have significant impacts on your current or future wellbeing or that of your family members. A material incidental finding concerning you in the course of this research will be communicated to you and to a health professional of your choice.

POSSIBILITY OF COMMERCIALIZATION

The results of the research derived in part from your participation in the study may lead to the development of new commercial products. However, you will not be entitled to any financial gain thereof.

FUNDING OF THE RESEARCH PROJECT

This research project is funded by the Department of Defense (DoD) through the Congressionally Directed Medical Research Program (CDMRP). DoD representatives may have access to research records as part of human subjects' protection oversight activities.

CONFLICT OF INTERESTS

The researchers have no conflict of interest to declare.

COMPENSATION

Your expenses for travel and parking fees related to your participation in this research study will be reimbursed after submission of receipts.

SHOULD YOU SUFFER ANY HARM

Should you suffer harm of any kind following any procedure related to this research study, you will receive all the care and services required by your state of health.

By agreeing to participate in this research study, you are not waiving any of your rights nor discharging the doctor in charge of the study, the sponsor, or the institution of their civil and professional responsibilities.

CONTACT INFORMATION

If you have any questions or if you have a problem you think might be related to your participation in this research study, or if you would like to withdraw, you may communicate with the lead researcher (Dr. Porter) at the following number: 514 934-1934 x37794 or by email: emily.porter@mcgill.ca.

For any question concerning your rights as a research participant in this study, or if you have comments or wish to file a complaint, you may communicate with the local service quality and complaints commissioner at: ombudsman@muhc.mcgill.ca.
For further information, you may also visit: https://muhc.ca/commissioner

OVERVIEW OF ETHICAL ASPECTS OF THE RESEARCH

The Research Ethics Board of the McGill University Health Centre has given ethics approval to this research study and is responsible for the ongoing ethics oversight of the study.

I have reviewed the Informed Consent form. Both the research study and the Informed Consent form were explained to me. My questions were answered, and I was given sufficient time to make a decision. After reflection, I consent to participate in this research study in accordance with the conditions stated above, including the use of all personal data and samples collected.

In addition, I authorize the researcher or research team to inform my family doctor or treating physician, in writing, that I am taking part in this research study and to send them all relevant information and/or incidental findings.

Yes ☐ Initials_____
No ☐ Initials_____

I authorize the researcher in charge of this study to communicate with me to see if I am interested in participating in other research studies.

Yes ☐ Initials_____
No ☐ Initials_____

Sex

Male ☐
Female ☐

Name of participant Signature Date

Participant Contact Information: Phone Email

SIGNATURE OF PERSON OBTAINING CONSENT

I have explained the research study and the terms of this Informed Consent form to the research participant, and I answered all questions asked.

Name of the person obtaining consent Signature Date