PARTICIPANT INFORMATION AND CONSENT
TO PARTICIPATE IN A RESEARCH STUDY

Title: **Preliminary Research Evaluation Ambulatory Leadless Electrocardiogram Recorder Trial (PRE-ALERT)**

Sponsor: HelpWear Inc.

Financial Support: HelpWear Inc. and Centre for Aging + Brain Health Innovation (CABHI)

Study Contact Information:

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Ask for the Electrophysiologist on-call

Before agreeing to participate in this research study, it is important that you read the information in this research consent form. It includes details we think you need to know in order to decide if you wish to take part in the study. This consent form describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. No guarantees or assurances can be made as to the results of the study. You should not sign this form until you are sure you understand the information. All research is voluntary. You may also wish to discuss the study with your family doctor, a family member or close friend. If you decide to take part in the study, it is important that you are accurate about your health history and any drugs you are taking. This will help prevent unnecessary harm to you.

The Principal Investigator received funding from the Centre for Aging + Brain Health Innovation for this study. The heart electrical signal or electrocardiography (ECG) devices are paid for from this funding. The amount of funding is sufficient to cover the costs of conducting the study.

1. BACKGROUND INFORMATION

This consent form should give you the basic idea of what the research is about and what your participation will involve. If you would like more details about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form.

You are being asked to consider participating in this research study because your doctor has determined that you should undergo 2 days (48 hours) or 3 days (72 hours) of extended ECG monitoring as part of your normal health care. The length of monitoring and device used (Holter, 48 hours or Event Recorder, 72 hours) will depend on the reason(s) your doctor has prescribed this testing.

Overall, this study will run for about 1 year. Your involvement in the research study will last for 48 to 72 hours.

Extended ECG monitoring is commonly performed in people with known or suspected heart rhythm problems. It typically involves the use of a portable recording device for 48 hours (Holter) or 72 hours (Event Recorder). These devices use small adhesive patches attached to your chest that are connected to the recording device via wires. Your heart's electrical signals are stored by the device, and then transmitted to a computer program for analysis by a technician, and interpretation by a physician. HelpWear has developed the HeartWatch armband device that collects ECG signals from your left upper arm or bicep, without the use of wires or patches. The signals are wirelessly (Bluetooth) transmitted to a smartphone, then transmitted from the phone to a computer program for analysis by a technician, and interpretation by a physician. The HeartWatch device is investigational in Canada, meaning that is has not been approved by Health Canada for use outside of a research study. Health Canada has reviewed and authorized its use in this study.

The testing devices (Holter, Event Recorder, HeartWatch and phone), as well as the computer programs for ECG analysis, will be provided to the study doctor by HelpWear if their clinic does not already have the necessary equipment to collect and analyze the ECG signals.

2. PURPOSE OF THE RESEARCH

The purpose of the PRE-ALERT study is to compare the clinical value (interpretability) of ECG signals collected from a Holter or Event Recorder with those collected from the HeartWatch arm band to see if the HeartWatch can produce reliable clinical ECG data.

In order to compare the same signals, you will be required to wear both a HeartWatch and a Holter for up to 48 hours or both a HeartWatch and an Event Recorder for up to 72 hours.

3. DESCRIPTION OF THE RESEARCH

If you agree to take part in the study, you will be one of about 50 participants at the Toronto Heart Center and St Michael's Hospital . The study involves the collection of heart electrical (ECG) signals using two devices at the same time. One is a medical device used as part of your standard of care. The other is the HeartWatch arm band.

4. STUDY PROCEDURES

Your participation in the study will last for 48 to 72 hours. After the testing is complete and you return the ECG monitor you will be asked if you had any issues using either of the ECG devices, which device, if any, you preferred, and whether you had any problems (e.g., rash) from the

devices tested. You will be contacted by telephone 1 to 3 days after the testing is completed and asked if you had any problems that began later.

Table outlining study procedures

Study Requirement	**Screening Visit**	**ECG Monitoring**	**Follow-up**
Length of time needed	1 hour	48 to 72 hours	15 minutes
Informed consent	X		
Medical history and medications	X		
Eligibility criteria assessment	X		
Reason(s) for ECG testing	X		
Activities during ECG testing		X	
Symptoms during ECG testing		X	
Problems related to ECG testing		X	X
Usability of ECG tests		X	
Preference, if any, of the ECG tests		X	

Screening Visit:

You will have been informed of all aspects of the study and will be asked to sign and date this consent form should you wish to participate in this study.

You should expect the following to occur at this visit:

- Review of your demographic information such as age and sex
- Review medical history, both general and heart rhythm-related
- Review of your current medications
- Reason(s) for your extended ECG testing

This visit will take approximately 1 hour

ECG Monitoring Phase:

You will have the function of the devices explained to you and given instructions for their use. This will include how to record your symptoms, how to remove or re-attach the devices if necessary, who to contact if you are having issues with their use, and where and when to return the devices. When you return the study devices you will be asked about your experience with the devices and your preference, if any, of the devices being evaluated.

You should expect the following to occur in this phase:

- Device placement
    - Placement of the devices by the research team
    - Instructions on the use of the devices, including removal and re-attachment
    - Instructions on how to document your symptoms

- ECG data collection
    - Wearing the devices for the specified length of time
    - Documenting your activities (walking, sitting, laying down, standing, etc …)
    - Documenting your symptoms
- Device return
    - Review of symptoms and symptom recording during ECG testing
    - Usability of ECG tests
    - Preference, if any, of the ECG tests

This phase will take approximately 24 to 72 hours

Follow-up Phone Call Visit:

You will be phoned 1 to 3 days after you return the devices and asked if you have had any subsequent issues since returning the devices. Specifically, any issues related to the location that the devices were placed.

This visit will take approximately 15 minutes

Additional Information

Because we need to know the details of your health during the study, you may be asked to help us get information from doctors or any hospital or clinic that you visit while you are in this study.

5. PARTICIPANT RESPONSIBILITIES:

It is your responsibility to inform the study staff of the following to ensure your safety throughout the study:

- Your participation in any other research studies as it may affect your participation in PRE-ALERT STUDY.
- Ask your study doctor if you have any questions or concerns.
- Tell your study doctor if anything about your health has changed.
- Report all changes in your physical condition while in this study, whether or not you feel they are related to the study.

6. POTENTIAL HARMS (INJURY, DISCOMFORTS OR INCONVENIENCE)

Heart Monitor Tests: It is possible that you may experience skin irritation from the standard ECG monitors or the armband. This is more likely to occur from the gel patches used for the standard ECG monitors than the arm band. Approximately 1 in 50 (2%) people develop skin irritation from the gel patches. Most of the time this is minor redness than goes away in a few days. You will not be able to swim, bathe or shower while wearing any of the monitors. You will be instructed on how to remove and re-attach the monitors so that you can swim, bathe or shower during the study period.

7. REPRODUCTIVE RISKS

There are no known risks of the study related to pregnancy. A pregnancy test is not required. There may be additional risks related to study participation that are unknown at this time.

8. POTENTIAL BENEFITS

There is no intended direct benefit to you for participation in this study. However, the knowledge gained from your participation may benefit other people in the future.

9. ALTERNATIVES TO PARTICIPATION

This study is not looking at ways to provide medical treatment to you, so the alternative to taking part in this study is not to take part. Whether you choose to take part in this study or not, you will receive the same standard and level of care.

10. PROTECTING YOUR HEALTH INFORMATION

All persons involved in the study, including the study investigators and coordinators (hereby referred to as "study staff"), are committed to respecting your privacy. No other persons will have access to your personal health information without your consent, unless required by law. The study personnel will make every effort to keep your personal health information private and confidential in accordance with all applicable privacy legislations, including the Personal Health Information Protection Act (PHIPA) of Ontario.

Personal health information is any information that could be used to identify you and includes your:

- Name,
- Date of birth,
- New or existing medical records, which includes types, dates and results of medical tests or procedures.

Any personal identifying information (such as your name) will be "de-identified" by replacing your personal identifying information with a "unique code/number". Only de-identified data will be sent to the Sponsor. The principal investigator at your hospital is in control of the study unique code key, which is needed to connect the study data to you. The link between the study number and your personal identity will be safeguarded by the principal investigator at St. Michael's Hospital.

To protect your privacy, data will be password-protected and securely stored. In addition, access to records and data will be limited to authorized persons and transmission of the data will be secure.

The study personnel and Sponsor, HelpWear, will use your de-identified study information to conduct the study and to support applications for approval of the study. HelpWear and its representatives may also use the non-identifiable health information collected in this study to improve the HelpWear product design and functionality. However, your name and other identifiable information will never be collected or used in another way. When the results of the study data and copies of your relevant medical records are provided to HelpWear and its representatives they will not include your name or any identifying information

By signing this form, you are authorizing access to your medical records by the study personnel, study Sponsor, Unity Health Toronto Research Ethics Board (this will be referred to REB for the remainder of the consent form) and by applicable government regulatory authorities (i.e., Health Canada). Such access will be used only for the purpose of verifying the authenticity and accuracy of the information collected for the study, without violating your confidentiality, to the extent permitted by applicable laws and regulations

You will not be named in any reports, publications, or presentations that may come from this study. De-identified information may be sent within Canada to the Centre for Aging + Brain Health Innovation (CABHI), who have provided financial support for the study. The information will be sent in "aggregate" meaning that the data will be summarized.

If you decide to withdraw from the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission, unless required for your safety.

If the results of this study are presented or published (i.e., in the medical literature), you will never be directly identified.

By Health Canada regulations, the study investigators will keep your study records securely stored for 25 years. After the study is finished, your records will remain at St. Michael's Hospital for 2 years then shipped offsite to Iron Mountain for the remaining 23 years. Iron Mountain is a data and records management company that is compliant with Health Canada and privacy regulations.

Risks of a privacy breach

It is important to understand that despite the protections described in this section being in place, there continues to be the risk of an unintentional release of information. The chance that personal information or study data will be accidentally released or accessed without authorization is small. The research ethics board and Privacy Office will be notified in the event of a privacy breach.

STUDY REGISTRATION AND STUDY RESULTS

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. Similar online postings of this clinical trial may also be required in other countries. No information that can identify you will be included in any such posting. Please talk to your study doctor or the study staff if you have any questions about this requirement.

The registration number for this study is NCTXXXXXXXX (registration pending – in progress).

11. STUDY RESULTS

The results of this study may be presented at conferences and may be published in scientific journals. Results will be published about the study population as a whole; neither your name nor your identifying information will be used. If you are interested in obtaining the results of the study, you can contact the investigators or research team. We estimate that the results of the study will be available in 1 year.

12. COMMUNICATION WITH PRIMARY CARE OR TREATING DOCTOR

By signing the consent form you give permission to the study staff to contact your family physician (and your other health care providers) to inform them of your participation, to enable your family physician to make informed decisions about your care and to obtain additional medical information.

13. ACCESSING AND COLLECTING INFORMATION FROM YOUR MEDICAL RECORD AT OTHER INSTITUTIONS OR PROVIDERS

By signing this form, you are giving us permission to access to your medical records held by other institutions or health care providers. These other institutions or 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 Visits and Research Activities section*. The study personnel will use this information to conduct the study.

On the signature page of this consent form, you will be asked whether you consent to allow the study staff to contact your family physician to inform them of your participation in this study. This will help your family physician to make informed decisions about your care.

14. POTENTIAL COSTSAND REIMBURSEMENT

You will receive a $10 gift card for your participation in this research study.

All testing and services performed only because of the study will be provided at no cost to you. There are no additional anticipated expenses for participating in the PRE-ALERT Study.

15. COMPENSATION FOR INJURY

If you become ill or if you are physically injured as a direct result of participation in this clinical study conducted in accordance with the clinical investigation plan, medical treatment will be provided in the same way you would normally receive medical care. You do not waive any legal rights nor relieve the physicians, or involved institutions from their legal and professional responsibilities.

16. PARTICIPATION AND WITHDRAWAL

As a trial participant you will be expected to:

- Follow the directions of the study doctor(s);
- Report all drugs being taken or that you plan on taking
- Report any changes in your health to the study doctor(s) and
- Report any problems you experience that you think might be related to participating in the study.

Your participation in this study is voluntary. You may choose not to participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on you or your family's future medical care. The care that you receive for your condition will not be changed if you decide to participate in this study

If you do decide to take part you may change your mind at any time without your medical care or legal rights being affected and no new information about you will be collected, except for safety data. This data will then be added to your existing data. Your consent with respect to the collection, transfer and use of your personal data generated up to that time period will remain valid and cannot be revoked.

If you do not want any safety data to be collected after the withdrawal of your consent, you must state this to your doctor. The study, and also your participation in the study, may be stopped earlier than expected, for example for scientific or safety reasons.

You may be taken out of the study by the study Sponsor, Health Canada, the study doctor or the Research Ethics Board at any time, if:

- You do not follow the directions of the study doctor
- In the opinion of the study doctor you are experiencing side effects that are harmful to your health or well-being
- There is new information that shows that being in this trial is not in your best interests. In this case, he will explain the reasons and arrange for your care to continue. The sponsor may also terminate this study at any time without your consent
- The study Sponsor, Unity Health Toronto Research Ethics Board, Health Canada or the study doctor decides to stop your participation, patient recruitment or cancel the study at any time.

You will be informed of any new findings acquired during the course of the study which may influence your decision to maintain your participation in this studyand asked to sign a form indicating your decision to continue or not.

17. NEW FINDINGS OR INFORMATION

We may learn new things during the study that you may need to know. We can also learn about things that might make you want to stop participating in the study. Sometimes during the course of a study, new information becomes available that might change your decision to be in this study.

18. STUDY CONTACTS

Immediately report any discomforts, problems, or injuries you experience during the course of your participation in the study to the **Research Coordinator, Zana Mariano at 416-864-6060 x 2696** However, if you have any side effects or a research-related injury and emergency medical treatment is needed, you should seek medical attention immediately and contact the study Investigator, **Dr. Paul Dorian at 416.864-5104** as soon as possible.

19. RESEARCH ETHICS BOARD CONTACT

If you have any questions regarding your rights as a research participant, you may contact **Dr. David Mazer, Chair, Research Ethics Board at 416.864.6060 ext 42557** during business hours.

The study protocol and consent form have been reviewed by a committee called the Research Ethics Board at Unity Health Toronto. The Research Ethics Board is a group of scientists, medical staff, and individuals from other backgrounds (including law and ethics) as well as members from the community. The committee is established by the hospital to review studies for their scientific and ethical merit. The Board pays special attention to the potential harms and benefits involved in participation to the research participant, as well as the potential benefit to society.

This committee is also required to do periodic review of ongoing research studies. As part of this review, someone may contact you from the Research Ethics Board to discuss your experience in the research study.

20. ATTESTATION

The principal investigator, co-investigators, and research staff do not have any conflicts of interest, financial or otherwise, related to this study or its' outcome.

You should be aware that it is possible that the study investigators, Drs. Dorian and Angaran, may also be your treating doctors."

Preliminary Research Evaluation Ambulatory Leadless Electrocardiogram Recorder Trial (PRE-ALERT)

Consent

The research study has been explained to me, and my questions have been answered to my satisfaction. I have been informed of the alternatives to participation in this study. I have the right not to participate and the right to withdraw without affecting the quality of medical care at St. Michael's Hospital for me and for other members of my family. As well, the potential harms 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 investigators, sponsors, 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 the study. I have been told that records relating to me and my care will be kept confidential and that no information will be disclosed without my permission unless required by law. I have been given sufficient time to read the above information. I consent to participate. I have been told I will be given a signed copy of this consent form.

FAMILY PHYSICIAN CONTACT: I agree that my primary physician will be informed of my participation in the study. ***Please check the box and initial***: ☐ ____ Yes ☐ ____ No

_____

Printed Name of Participant

_____ _____

Signature of Participant Date (DD-MMM-YYYY)

_____

Printed Name of Person Obtaining Informed Consent

_____ _____

Signature of Person Obtaining Informed Consent Date (DD-MMM-YYYY)