Participant Information and Consent Form

Vancouver CoastalHealth
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Protocol Title:	Standard versus Intensive Monitoring Post-Myocardial Infarction Looking for New-Onset Atrial Fibrillation **(SIMPL-AF)**
Principal Investigator:	Dr. Jason G Andrade
Co-investigators:	Doctors: Christopher C. Cheung, Kenneth G. Gin, Andrew D. Krahn, Marc W. Deyell. Research Managers: Jackie Chow, Andrew Starovoytov, and Karen Gibbs. Operations Manager: Faisal Aziz. All investigators are members of the Vancouver Hospital Division of Cardiology and the Department of Medicine of the University of British Columbia (UBC).
Funding:	This project is supported by the Canadian Cardiovascular Society-Bayer Resident Vascular Research Award and the UBC Division of Cardiology.

Invitation and background

You are being invited to take part in this research study because you had a myocardial infarction (heart attack) and are being discharged home. Patients who suffer a heart attack are at higher risk for developing a cardiac arrhythmia (irregular heart beat) after leaving the hospital. An area of the heart damaged during a heart attack may create abnormal electric currents, causing the heart to work very fast or slow. These arrhythmias can lead to palpitations (feeling of heart racing), fainting, and some could be life threating. Because of these arrhythmias, patients in the hospital wear cardiac monitors and are observed for at least 2 days.

Although all patients will receive cardiac monitoring during their hospital stay, cardiac monitoring is currently not available once patients are discharged home. Without monitoring at home, patients may develop an arrhythmia that is not detected or unrecorded. Since the arrhythmia may only happen from time-to-time, they may not be detected by periodic monitoring or appointments with the family doctor or cardiologist.

Atrial fibrillation (irregular beats from the upper chambers of the heart) is the most common type of arrhythmia after a heart attack. Atrial fibrillation can lead to a sensation of palpitations, and over the long term, can also increase the risk of suffering a stroke. Individuals who develop atrial fibrillation may benefit from the initiation of a blood thinner (anticoagulant) to reduce the risk of stroke.

In this research study, individuals will be randomly assigned to receive an additional 30-day continuous monitor or standard medical care. Two-thirds the participants will be randomly assigned to use the 30-day continuous monitor to detect cardiac arrhythmias upon discharge from hospital. The monitoring results will be shared with your primary cardiologist and family physician, and you will also have access to the information after collection is completed. The information will tell us more about what happens to your heart rhythm after going home, and whether you have any cardiac arrhythmias, including atrial fibrillation. We plan to enroll 240 subjects at Vancouver General hospital.

Your participation is voluntary

It is a basic requirement of clinical research that a person who participates in the study of a new medical condition or treatment gives his or her informed consent to such participation. This consent must be based on an understanding of the procedures and risks involved. Please take your time in making your decision. If you decide to participate you will be asked to sign the last page of this

form. You may choose not to participate, or you may withdraw from participation in the study at any time after you are enrolled without providing any reason. In either case, your standard medical care will not be affected by this decision

Who is conducting the study
This study is conducted by Dr. Jason Andrade and a group of cardiologists under the University of British Columbia (UBC). This project is supported by the Canadian Cardiovascular Society-Bayer Resident Vascular Research Award and the UBC Division of Cardiology.

Who can participate in this study
Your medical history will be reviewed to determine that you meet all the criteria to participate in this study. The study doctor or staff will discuss them with you. You can participate if you:

- Are 18 years or older;
- Had a heart attack during this hospital admission;
- Have no past history of atrial fibrillation;
- Are not taking anticoagulants (type of blood thinner medication) for another reason

You should not participate if you:

- Have a chronic skin disorder on your upper torso;
- Are allergic to medical tape or glue;
- Received cardiac surgery (bypass surgery) during this hospitalization or have planned cardiac surgery within the next 3 months;
- Had an atypical heart attack or disorder (called “spontaneous coronary artery dissection”, “non-atherosclerotic coronary disease” or “Takotsubo cardiomyopathy”);
- Are unable to take anticoagulation (type of blood thinner medication) for any reason

What does the study involve?
If you agree to participate in the study we will ask you sign this consent form before you leave the hospital. You will be randomized (like flipping a coin) and assigned to one of two groups: the standard of care group (without extra monitoring) or monitored group.

Subjects in the monitored group will be trained on how to apply and use the SpiderFlash 30-day monitoring device prior to leaving the hospital. SpiderFlash is small medical device with three electrodes (wires) attached to your skin with special stickers. We ask that you disconnect the device and wires during showering, bathing, and swimming. You will be provided with extra stickers to reconnect the device, if any leads fall off. This device will begin recording your heart’s electrical activity (ECG or electrocardiogram) immediately and will continue for the next 30-days.

If you are randomly assigned to receive the SpiderFlash device, you will receive training on wearing the device for the first time. This training will take between 30-60 minutes and will occur during your hospital stay. At home, routine changing of the leads is anticipated to take 5-10 minutes per day.

Irrespective of the group (monitoring or standard of care) you are randomized to, you will receive a diary prior to leaving hospital. In the diary, you can take notes of any symptoms you may experience over the next 30 days.

After 30 days we will ask you to return the device and diary to the Cardiology Research Office at the Gordon & Leslie Diamond Health Care Centre. Your monitoring device will be analyzed and reviewed by the study investigators, and all results will be forwarded to your primary cardiologist and family physician. You will be asked about your current symptoms and any new health issues or hospital visits. We will also collect names of you current cardiac medications. This visit will take approximately 40 minutes of your time.

At 3 months and 1 year after your discharge you will be contacted by phone to review your current symptoms, new health problems and review your cardiac medications. This phone interview will take 15 minutes. At this time, your health records will also be reviewed for prescription information, electrocardiograms, new health issues, and hospital visits. You will have to dedicate about a total

of 2 hours beyond that required for standard treatment (not including travel time) to complete the study.

What if the monitor detects an arrhythmia?
If you are randomly assigned to receive the 30-day monitor, the monitoring results will be forwarded to your primary cardiologist and family physician. If atrial fibrillation is detected, your primary cardiologist and family physician will have this information and treat you accordingly. Although patients with atrial fibrillation may benefit from taking a blood thinner (anticoagulant) to prevent stroke, this should only be started if it is considered safe in your circumstance. Thus, these medications will not be started as part of the research protocol. The final decision will be made by your primary cardiologist or family physician. If the 30-day monitor detects any other arrhythmias, your primary cardiologist and family physician will also have this information and treat you accordingly.

What are the possible harms and discomforts?
Potential risks associated with participation in this study are discomfort, redness or irritation under the electrodes when using the SpiderFlash device. We will simply ask you to disconnect the device if it causes you significant skin discomfort.

What are the potential benefits of participating?
You may not have any direct benefits from this study. You may experience better care from specialists, however, this is not guaranteed. You may be contributing to the medical knowledge about your heart condition. Information regarding any important changes discovered with your monitoring device will be forwarded to your doctors.

What if new information becomes available that may affect my decision to participate?
You will also be advised of any new information that becomes available that may affect your willingness to remain in this study.

What are the alternatives to participating?
If you chose not to participate in the study and develop symptoms of irregular heart-beat your doctor might give you a similar type of a monitoring device called a Holter monitor. There will be no disadvantages should you decide not to participate in this study.

What happens if I decide to withdraw my consent to participate?
Participation in this study is voluntary. If you decide not to participate, this will not affect your medical care. You may discontinue participation in the study at any time without penalty or loss of benefits to which you are otherwise entitled. The Investigator will retain any data collected up to the point of a subject's withdrawal from the study such that the data itself cannot be withdrawn. In no way does signing this form waive your legal rights, nor relieve the investigator or involved institutions from their legal and professional responsibilities.

How will my taking part in this study be kept confidential?
Your confidentiality will be respected. However, research records and health or other source records identifying you will be inspected in the presence of the Investigator, or his or her designate, by representatives of the UBC Clinical Research Ethics Board for the purpose of monitoring the research. By signing this form you are authorizing such access to your medical records. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your

research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected. You also have the legal right of access to the information about you that has been provided to the sponsor and, if needed, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor

What happens if something goes wrong?
Since no experimental treatment will be used in this research study, we do not anticipate any side effects as a result of participating in this study. By signing this form, you do not give up any of your legal rights and you do not release the study doctor, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan.

What will the study cost me?
All research-related tests that you will receive during your participation in this study will be provided at no cost to you. You will not be paid for your participation in the study.

Who do I contact if I have questions about the study during my participation?
If you have any questions or desire further information about this study before or during participation, you can contact Lily Cai, Research Assistant at 604-875-4111 ext. 66463. Please reference the study number H17-01060 when calling so the staff can better assist you.

Who do I contact if I have any questions or concerns about my rights as a participant?
If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

After the study is finished
The study results will be compiled and reported in a medical journal. 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.

Standard versus Intensive Monitoring Post-Myocardial Infarction Looking for New-Onset Atrial Fibrillation (SIMPL-AF) **Participant Consent**

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have had enough time to think about the information provided.
- I have been able to ask for advice if needed.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
- I authorize access to my health records as described in this consent form.
- I understand that I am not waiving any of my legal rights as a result of signing this consent
- I understand that there is no guarantee that this study will provide any benefits to me.

I consent to participate in this study

_____	_____	_____
Name of Participant:	Signature:	Date

I have explained the purpose of this research, the study procedures, identifying those that are investigational, the possible risks and discomforts, as well as the potential benefits and have answered any questions regarding the study. The subject meets all inclusion and exclusion criteria for the study and freely agrees to participate.

_____	_____	_____	_____
Person Obtaining Consent:	Signature	Study role	Date

_____	_____	_____
Principal Investigator or designated representative	Signature:	Date

Was the participant assisted during the consent process in one of ways listed below? ☐ Yes ☐ No

☐ The consent form was read to the participant, and the person signing below attests that the study was accurately explained to, and apparently understood by, the participant.

☐ The person signing below acted as an interpreter/translator for the participant, during the consent process (please check if an interpreter/translator assisted during the consent process).

☐ If this consent process has been done in a language other than that on this written form, with the assistance of an interpreter/translator, indicate language: _____

_____	_____	_____
Signature of Person Assisting in the Consent Discussion	Signature:	Date