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CONSENT FORM
Home-based Videopethysmographic (VPG) detection of atrial fibrillation

Principal Investigators: Dr. Spencer Rosero (MD, URMC)
Sub-Investigator: Drs. Jean-Philippe Couderc (PhD, URMC)

This consent form describes a research study, what you may expect if you decide to take part in the study, and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Before you agree to participate, please ask questions about anything that is not clear. You may take this consent form home to think about your participation in the study, and discuss it with family or friends.

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time.
- If you choose not to take part, your routine medical care will not be changed in any way.
- There are risks associated with participating, and you should understand what these mean to you.

Introduction

You are being asked to take part in this study because you have been diagnosed with atrial fibrillation (AF), an abnormal heart rhythm, and are already scheduled to have a cardioversion or an ablation procedure (a medical procedure done to restore a normal heart rhythm) as part of your routine care.

This study is being conducted by Spencer Rosero, MD , and Jean-Philippe Couderc, PhD of the University of Rochester's Department of Cardiology.

Purpose of the Study:
The purpose of the study is to evaluate the ability of video-based technology to detect the presence of atrial fibrillation. We will measure and compare electrical signals from the heart and video images of the face and index finger in adults with atrial fibrillation after their cardioversion or ablation procedure for a period of 2 weeks. If you have atrial fibrillation, this will be done after your procedure. Electrocardiograms (ECG - recordings of the electrical activity of the heart) will be recorded during 2 weeks using an ECG patch. You will be asked to wear the patch during this period. The study is a collaborative project among the University of Rochester Medical Center (URMC), the Rochester Institute of Technology (RIT), and funded by the National Institute of Health.

Description of the Study Procedures:
The study involves the use of the following two devices for a period of 2 weeks following your treatment for AF. A study staff member will put an ECG patch on your skin that records the electrical activity of your heart for a period of 2 weeks. Also, you will receive a Tablet Computer to be used for reading, watching TV series and movies, responding to your email, or browsing the internet. While you are doing these activities the tablet will record videos of your face and extract information about your heart pulse. During the study and during periods of symptoms we will also ask you to record a video of your index finger. The videos of your face & finger, and information about your pulse, are called Videopethysmographic (VPG) signals. The use of the Tablet will be explained to you before your procedure, and you will have the possibility to reach technical support as needed (Dr. Jean Xia at 585-275-0691). No other person should be using the tablet during the 2-week period.

1. Prior to your procedure (cardioversion or ablation) a study staff member will ask you questions regarding your general medical history, current medications, and past AF symptoms. Completing this questionnaire should take less than 5 minutes.

2. After your procedure (prior to your discharge) an ECG patch will be put on your torso to monitor your heart for a period of 2 weeks. This small device is worn while you are conducting your normal daily activities. You can bathe and shower with the device.

3. After your procedure (prior to your discharge) we will give you a smart tablet

computer that you can use at home for browsing the internet, reading, watching shows, and responding to your emails. The device will monitor your heart pulse while you are conducting these activities.

4. Prior to your procedure and discharge to home, study staff will provide you with training about the ECG Patch, AF Symptoms, how to use the Tablet VPG and Symptoms applications, and the general use of the Tablet.

5. A study staff member will contact you within 48 hours after you've returned home to verify that the Tablet could be connected to your home WIFI system, to ask you a series of survey questions regarding the training given to you prior to your discharge, and to obtain your feedback as to whether you feel you may require additional training support. The survey is very short and will take less than 5 minutes.

6. With your home internet access, we ask that you spend at least 30 minutes twice a day utilizing the tablet (a total of 60 or more minutes) for browsing, e-mails, reading, or watching shows. This is a very important component of the research study that will provide critical information about the ability to detect episodes of Atrial Fibrillation with the tablet's video-based technology.

7. In addition to the activities noted in 6 above, you will need to record two 30 second videos of your face and finger each day. The two recording sessions should be at least 6 hours apart and have the first session in the morning. The tablet Notification Application will notify you up to four times as a reminder to do the two scheduled recordings.

8. You will also be instructed in how to record videos of your face and index finger whenever you experience AF symptoms. This will be accomplished through your use of a Symptoms application (APP) available on the Tablet, which will ask you to select your symptoms from a displayed list of symptoms. Based upon your selection of symptoms, the Symptoms APP may recommend that you contact your doctor or seek other medical attention to help relieve your symptoms and possibly prevent further medical complications. Use only the Symptoms APP on the Tablet to record your symptoms. Do not use the paper diary to record symptoms.

9. You cannot download or install novel applications on the tablet (the tablet will

be disabled for application download).

10. An automatic report verifying the stability of the recording technology will be sent to the study center every day (via your home internet access). A study staff member will contact you in case any of the monitoring technologies are performing outside expected values.

11. Technical support is available by phone through the CAMAFIB study at 585-275-5391.

12. You should be the only one to use the tablet.

13. We will contact you on or about the end of the 14-day study period to go over the ECG Patch removal process; how to mail back both the tablet and patch via a pre-addressed, pre-paid study package. This will take less than 5 minutes.

Enrolling in the study will not modify/affect the conduct of your scheduled Atrial Fibrillation treatment procedure by your personal physician.

Any information that is obtained in connection with this study and that can identify you will remain confidential. To protect your confidentiality, health information such as your ECG and Videopethysmographic (VPG) signals will be labeled and stored using a code that is unique to you. When we disclose your health information to other researchers or commercial entities, it will be protected through the use of this special code ("coded information"). Only the study doctor and members of the research team at the URMC will be able to match the code to your name, date of birth and other data that is typically used to identify you. Personal identifiable video images of your face that are collected during the study will remain confidential and not be shared outside of the URMC study group.

Number of Subjects
Approximately 315 cardiac subjects will take part in this study.

Length of Participation:
You will be involved in the study for two weeks.

Risks of Participation:
There is minimal risk associated with a single lead ECG patch. There is a possibility of skin irritation such as redness, severe itching or allergic symptoms (i.e. hives) due to the placement of the ZIO® XT Patch on your skin. If skin irritation such as severe redness,

itching or allergic symptoms develop and persist during the recording period, you should remove the ECG patch from your chest and contact the Study Staff (that attached the patch) for any additional instructions/support. You will also be encouraged to subsequently advise your primary Care physician that you may have an allergic reaction to medical adhesives. If significant skin irritation persists or if your skin has blistered, you should seek medical treatment.

Each recording made on the tablet will be associated with a unique identifier to avoid privacy breach. There is minimal risk associated with the video recordings and VPG monitoring of your face and finger. Your full face will be recorded on the video. To protect your privacy, these images will not be shared outside of the University of Rochester. They will be stored in a secure server with access limited to UR study personnel. The recording of your finger uses the Tablet's flashlight feature through the camera lens on the back of the Tablet to obtain pulse information via the light passing around and through your finger, and involves little or no risk.

A breach in confidentiality is a risk of participating in this study. As noted above, it will be minimized by assigning a specific code number to study data and removing personal identifying information. Access to study data with personally identifying information will be limited to study personnel at the URMC only. De-identified study data will be shared with investigators at RIT. There is a potential for data loss/hacking for the facial images going through the web. Although this potential is minimal, we have imposed the following processes to protect the data: The video recordings will be deleted automatically from the tablet after processing and one single image of the face will be kept and associated with the recording measurement. These two pieces of information will be gathered in a single encrypted file. This file will be stored on the tablet and transmitted to a cloud server (BOX.com) using encryption schemes. Therefore, the data recorded with the Tablet are encrypted and moved and stored using devices that are password-protected in order to secure the subject privacy. Data access will be granted only to the individuals involved in the project. Data will be stored in a secure server at the University of Rochester with access limited to study personnel. The cloud server used to host the 30-sec recordings is a Box.com server that is password protected.

Importantly, the facial video images will not be shared with the other organizations (outside of the URMC) in this study in order to protect the privacy of the study subjects. Signals without personally identifying information (VPG only) will be shared with the study collaborators (RIT). All data will be de-identified by URMC to comply with the HIPAA "Safe Harbor" method of de-identification set forth at 45 CFR 164.514(b) prior to disclosure to RIT's investigator. Signed consent forms will be stored in a locked file cabinet with access limited to study personnel. Data will be stored indefinitely.

Benefits of Participation

You will not benefit from being in this research study.

Your electrocardiographic information will be reviewed by ECG experts or a cardiologist, and you will be contacted if the results indicate you should see a physician.

Funding Support

The University of Rochester is receiving payment from the National Institutes of Health (NIH) for conducting this research study.

Costs

There is no cost to you to participate in the study.

Payments

You will be paid $100 (by check) if you complete the 14 day study period. No pro-rated payments will be available if you withdraw before the end of the study period.

Financial Interests

Dr. Jean-Philippe Couderc U of R Sub-Investigator on this study has financial interests in the technology used in this study. Please feel free to ask any questions you might have about this interest.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the personally identifiable information collected from you private. In order to do so, your research information will be securely stored in a coded fashion. Paper documents and records will be stored in a secured location with access restricted to authorized personnel only. Electronic study documents and data will be kept in a password-protected environment. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators, or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Research video and ECG recordings
- Research records

- Records about phone calls made as part of this research

Who may use and give out information about you?
- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:
- The U.S. Department of Health and Human Services
- The University of Rochester Medical Center
- The National Institutes of Health
- Rochester Institute of Technology.
- iRhythm LLC. (this company will extract the data from the ECG patch and send it to URMC)
- The U.S Food and Drug Administration (FDA) may also need to inspect study records at some point during the study or even after it has been completed. In the event that this should occur, every effort will be made to keep identifying information about you private.

Why will this information be used and/or given to others?
- to do the research,
- to study the results,
- to see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information? Then you will not be able to participate in this research study.

May I review or copy my information?
Yes, but only after the research study has been completed.

How long will this be permission be valid?
This permission will last indefinitely until revoked.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information; and you will not be allowed to continue in the study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

Contact Persons

For more information concerning this research or if you feel that your participation has resulted in any research related injury, or emotional or physical discomfort, please contact the Principal Investigator on this study**:**

Spencer Rosero, MD at (585) 275-4775
(24hrs)

Please contact the University of Rochester Research Subjects Review Board at:
265 Crittenden Blvd., CU 420628
Rochester, NY 14642-8315
Telephone (585) 276-0005 or (877) 449-4441

For the following reasons:

- To voice concerns about the research;
- To talk to someone other than research staff about your rights as a research subject
- To provide input concerning the research process;
- In the event the study staff could not be research

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

For UR employees: Taking part in this research is not a part of your University duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

Signature/Date

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have, instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form, and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____

Subject Name (Printed by Subject)

_____ _____

Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given, and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date