UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title:

An innovative study for patients with Atrial Fibrillation.

1.2 Company or agency sponsoring the study:

NIH

1.3 Names, degrees, and affiliations of the researchers conducting the study:

Principal Investigator: Hamid Ghanbari MD, MPH, Assistant Professor, Division of Cardiology, University of Michigan

Research Coordinators: Sangeeta Lathkar-Pradhan and Diana Paraschiv

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Atrial fibrillation is a type of irregular heart rhythm and symptoms vary among different people and common symptoms include fatigue, shortness of breath, palpitations, chest pain, weakness, and problems exercising. The purpose of this research study is to learn about association between symptoms of atrial fibrillation and functional status by continuous recording the heart rhythm and a new tool that is a mobile application called miAFib app that is developed at the University of Michigan.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Anyone who has atrial fibrillation can take part in this study.

3.2 How many people (subjects) are expected to take part in this study?

100 subjects are expected to participate in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you decide to take part in this study, we will first collect your health information, including your cardiac health and the medications you're taking.

We will ask you to wear one device on your body for 3 weeks and use a smart phone app.

Device:

You'll wear one device on your chest and abdomen all day long, except while bathing, showering, or swimming. This device is called a heart monitor and is made by either Lifewatch, Inc. or BodyGuardian® (Preventice). They have been approved by FDA and are used in standard medical treatment for AFib. The University of Michigan Health System often uses Holter monitors to treat patients. The Holter monitor will track your heart activity while you wear it. It will then send electronic information about your heart activity to Lifewatch/Preventice. At the end of the study, Lifewatch/Preventice will send us data relating to your heart activity. The event recorders that will be placed on the chest by the study team and returned once the study has concluded. This device also records your activity level, pulse and nervous system activity.

You will be using a touch screen cellular phone during the time you are wearing Lifewatch/BodyGuardian monitor. Please keep this cellular phone within 10 feet from the monitor.

After 3 weeks, you will return the device. We will ask you to mail the Lifewatch/BodyGuardian monitor to a data processing center using a postage-paid return box or in person (A member of the study team will help you with this) The processing center will then send us the data stored in the device. We will analyze the data and compare it with data from the other study device and the computer programs.

You will also complete paper questionnaires at two separate times: on the first day that you wear the Holter monitor and on the last day that you wear it.

Smartphone app:

You'll use a smartphone app called miAfib to record your daily symptoms. A member of the study team will help you install the app on your smartphone. About 3-4 times a day, you will use the miAfib app to rate the severity of the following symptoms and affect/emotion on a scale of 0 to 10:

- difficulty breathing (dyspnea)
- fatigue
- heart palpitations
- chest pain
- dizziness
- positive/negative emotion

miAfib app will send this information to our study website. No information will be stored on your smartphone. No information that directly identifies you (such as your name) will be transferred to the website.

You will be asked to rate the miAfib smartphone app, by answering 3 questions about ease of use.

Future Use of Samples and or Data:

We would also like your permission to study your data and medical information for future studies concerning heart rhythm, feelings and function. We will keep your data in a secure encrypted environment where only authorized study personnel have access to the data. Even if you give us permission now to keep some of your data and medical information, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your data, we may not be able to take the information out of our research. Parties involved may benefit financially from future research on your data and medical information.

You may still participate in this study even if you do not agree to participate in the data storage. Please initial one of the following sentences: (If you do not initial next to a statement we will assume your answer is no)

_____ YES, I give permission to allow investigators to maintain my data for future research,

_____ NO, I do not give permission to allow investigators to maintain my data for future research.

4.2 How much of my time will be needed to take part in this study?

20 minutes per day for 3 weeks. A total of about 70 minutes at the first visit to set up miAfib smartphone app, Holter monitor, and to complete the first questionnaire. A total of about 40 minutes at the end of the study visit for questionnaires.

4.3 When will my participation in the study be over?

After 3 weeks.

4.4 What will happen with my information and/or biospecimens used in this study?

Your collected information will be de-identified and may be shared with NIH the sponsor of the study and Preventice, the manufacturers of the heart monitor

With appropriate permissions, your samples and collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Holter Monitor: Skin discomfort or irritation due to the electrodes used in the continuous heart monitor.

Surveys; Sadness or distress is rare; you may refuse to answer any questions that make you uncomfortable. You can discuss such feelings of sadness or depression with your primary care team.

Risk of loss of privacy: It's possible that people outside the study might find out you've taken part or might see your information. To prevent this, we will label your information with a unique subject ID number, rather than your name or other information that others could use to identify you. Your personal information will not be shared on the questionnaires or symptom assessment information recorded by the smartphone app.

Only members of the study team at the University of Michigan will have access to the file linking your study number and your identity. Database files will be accessible by study members only through password protected computers/files and computers are located in locked offices.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

Patients participating in the study will directly benefit from their participation as they will benefit from the close monitoring of their AF symptoms. They will also gain greater insight into their disease by utilizing the mobile application, continuous ECG recording and functional status assessment using an accelerometer device. There are not additional costs for the patient if they participate in this study. They may also gain personal benefit and satisfaction by contributing to a research project aimed at improving patient care.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?

Your option is to simply not participate; it will not affect your medical care in any way.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information" (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

No, nothing about your medical care will change if you decide to leave before the study is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

In total, you will be given a VISA gift card worth a total of $50; $25 will be loaded at the first visit and another $25 will be loaded at the last visit; if you complete all study related activities.

8.3 Who could profit or financially benefit from the study results?

Dr. Najarian is an inventor on patents or patent applications for technology used in this study. This means that the University of Michigan and Dr. Najarian could one day benefit financially from this study.

In the interest of transparency, we would like you to know that Dr. Ghanbari has served as a consultant for the manufacturer of the BodyGuardian heart monitor. He is unlikely to benefit personally from the results of the study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?

If you decide to take part in this study, your medical records and personal information will be kept private to the extent allowed by federal, state, and local law. No personal information about you, your illness, or your treatment will be made public. A special code subject identification number will be used to identify your personal information.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Health plan/health insurance records
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly

  - Learn more about side effects
  - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)

- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: **Hamid Ghanbari MD**
Mailing Address: Cardiovascular Medicine, 1500 E. Medical Center Drive, SPC 5853, Ann Arbor, MI 48109
Telephone: 734-615-2680

Study Coordinator: **Sangeeta Lathkar-Pradhan**
Mailing Address: Cardiovascular Medicine, 1500 E. Medical Center Drive, F5351, Ann Arbor, MI 48109
Telephone: 734-232-5022

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies: US Country Code: 001)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.*

12. SIGNATURES

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with . My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____