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UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent: _____

Place of employment & position: _____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study (this "Research Study")?

ROAMM-EHR: Pilot Trial of a Real-Time Symptom Surveillance System for Post-Discharge Surgical Patients

3. Whom do you call if you have questions about this Research Study (the "Study Team")?

Principal Investigator: Todd M. Manini, College of Medicine, Phone: (352)-273-5914 (Cell 352-275-8670)

Research staff: Camesha Tate, College of Medicine, phone: (352) 2735916

4. Who is paying for this Research Study?

The sponsor of this study are the National Institute on Aging and the University of Florida.

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way, and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

UF IRB-01 Approved

a) In general, what is the purpose of the research? How long will you be involved?

The purpose is to learn if wearing a smartwatch to monitor symptoms and ailments is helpful for doctors to care for their patients after having surgery.

You will be asked to participate for approximately two months. You may be enrolled before or after your surgery. You will be asked to return for your close-out visit approximately 30 days after your surgery.

You will be randomly (like flipping a coin) placed into one of two groups. In group 1, patients will wear and respond to questions on a smartwatch. Responses will be sent to their doctor and medical team to review and decide if you need to be contacted for follow-up care. In group 2, patients will wear and respond to questions on a smartwatch. However, the information will not be reviewed by their doctor and medical team. You will not know which group you are assigned.

It is important for you to communicate with your surgeon and their team as if you did not have the smartwatch. In most cases, the doctor's team asks patients to communicate by telephone if there is an issue.

b) What is involved with your participation, and what are the procedures to be followed in the research?

This study is designed to learn whether reports of your symptoms from a smartwatch (e.g., Apple Watch) will help doctors and their team manage your post-surgical care. You will be asked to answer questionnaires about your health at baseline which can happen before your surgery or when recovering in the hospital after your surgery. You will also be asked to do some physical tests (walk, balance and chair rise) only if you are enrolled before your surgery. You will not be asked to perform physical tests after your surgery while recovering in the hospital. These tests will be repeated approximately 30 days after your surgery. You will be given a smartwatch about 1-2 weeks prior to your surgery. You will be asked to keep wearing the watch until about 30 days after your surgery. More details are given under section 7.

c) What are the likely risks or discomforts to you?

In general, the risks of participating in this study are low. When doing the clinical research measures, there is a small risk of falling and/or injuries (for example, spraining an ankle). To prevent injury, we do tests in a safe space with coaching from our study staff. We will only ask you to do tests that you are comfortable doing.

Also, some people might feel uncomfortable answering health questions and giving answers on the smartwatch. You may skip tests that make you feel uncomfortable or unsafe without harming your participation in the study.

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There are very little risks with wearing a smartwatch. Please do not use or answer questions on the smartwatch while driving, walking, or while doing other tasks that might interfere with your focus.

d) What are the likely benefits to you or to others from the research?

If you are selected to be in Group 1, your answers on the smartwatch and information from watch sensors may inform your doctor and their team about your symptoms. This information might be helpful to manage your care.

The findings from the study will help doctors understand if regular information about patient symptoms is helpful for better and faster recovery after surgery.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

This study does not provide treatment, and there are no alternative procedures. You may choose not to participate in the study.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?

Nothing in this study is part of your normal clinical care. If you decide not to participate, your care will remain the same at UF Health.

7. What will be done only because you are in this Research Study?

The measurement and activities in this research study fall under clinical research and smartwatch measures described below.

Clinical research measures done on the Baseline**:** These measures are done in-person with surveys and doing some physical tests. The visit will last about 2 hours.

Questionnaires about your health and lifestyle: These include demographic information, medical history, medications, daily activities, walking abilities, and related topics about your health and lifestyle. We will ask you about your pain experiences when doing some daily activities.

Tests of your physical function. These include tests of usual walking speed, balance ability, and sitting/rising from a chair. You will not do these tests if you are enrolled after your surgery.

We may ask you to come for an unscheduled visit or phone call. This could be necessary if equipment is not available, or you do not finish an entire visit or that you need extra education on how to use the watch. We may also ask you to mail

UF IRB-01 Approved

equipment to us if you are unable to return to the clinic. We will give a pre-addressed and paid envelope in cases when you need to return equipment by mail. We will also collect your email address to communicate and potentially send you electronic surveys.

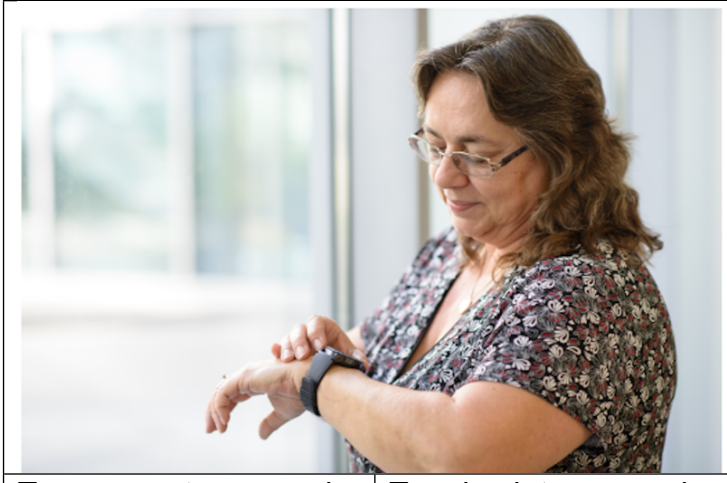
We will also ask your permission to access your medical record to check eligibility for the study, look for safety concerns, confirm your health history, and document any health occurrences before and after your surgery.

Below is a detailed description of what you will be asked to do at home:

We will give you a smartwatch to use for the duration of the study. We will ask you to wear the smartwatch like a regular wristwatch every day. You will take it off at night before you go to bed and put it on the charger.

See figure below. While wearing the smartwatch, it will ask you questions by prompting you with a vibration or sound. You will respond by turning the dial on the side of the smartwatch or by tapping on the screen. It should only take a few seconds to respond. The prompts will ask you to rate your symptoms, like current pain or fatigue level, and the medicines you took. You will also be asked about your ability to do everyday activities like walking and getting out of the chair. You may also get questions about your sleep quality, physical activity and other behaviors. After surgery, you will get similar questions as before the surgery and some extra ones that ask about your wound healing, rehabilitation activities and the medications you took for your wound, and any other health events that happened.

Overall, you should expect about 3-10 prompts to answer on the smartwatch per day. You will only spend a couple of minutes per day answering these prompts.



Tap screen to respond	Turn knob to respond



We will show you how to use the smart watch before you get it. If you are having any trouble with the smartwatch, please don't hesitate to call the study coordinator at the number posted on the first page.

Please do not answer prompts when you do not feel safe to look at the smartwatch. **DO NOT** answer a prompt when you are driving. Completely ignore the prompt if you are driving. If you are walking, please don't try to walk and answer questions. If possible, stop and answer the questions or ignore the notification. If you do miss a prompt, it will wait in the queue for a few hours to answer later.

The watch is connected to the internet and the global positioning system (GPS). It uses this information to measure your community mobility — how often and far you travel away from your home. We also collecting information from the sensors which measure your activity levels (steps per day) and some vitals (heart rate). These are collected in the background and do not need your input. The manufacture (e.g. Apple) does not collect or save data collected on the ROAMM smartwatch app. Data are saved indefinitely on our protected servers at the University of Florida and only accessible by the study team.

When you are wearing the smartwatch, please call us if you are having a technical issue with the smartwatch (e.g. no signal, receiving no questions). A study team member will be available during normal business hours to help you troubleshoot the problem. During your study visit, we will give you instructions on paper that will have phone numbers and contact information. You may also contact the research staff members listed in question 3 of this form.

People who enroll in this study are allowed to participate in other research studies. We do ask that you tell us and inform the other study investigators about your co-participation.

Once this research study is completed, any information that could identify you might be removed from any identifiable private information. After such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you If any identifiable information <or identifiable biospecimens> <was/were> collected as part of this research, it is possible that your research information <or specimens>, with all personally identifiable information removed, could be used for future research

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studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

8. What identifiable health information will be collected about you and how will it be used?

The Research Team will collect:

- Name
- Contact information (phone number, address and electronic communication)
- Date of Birth
- Medical record number
- Information about your health and medical history from your medical record or through a survey
    - Disease and diagnosed health conditions
    - Hospitalizations and medical events
    - Recent procedures
    - Medications
    - Blood work
- Information about your surgery
    - Type of surgery
    - Length of stay in the hospital
    - Medications related to surgery
    - Post-surgery care treatments
- Email address and phone number to communicate
- Location from the smartwatches
- Caregiver's contact information (with you permission) to inform them about the study and your participation

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals, or clinics). Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

The IRB that reviewed this Research Study ensures your rights as a Study Subject are protected. This health information may be shared with:

- The study sponsor (listed in Question 4 of this form).

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- United States governmental agencies which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections.
- Government agencies which are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state, and local health departments and
- the IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected.

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this Research Study?

You will be asked to participate for approximately two months. You will be enrolled a few weeks prior to your surgery. You will be asked to return for your close-out visit approximately 30 days after your surgery.

11. How many people are expected to take part in this Research Study?

We expect to screen 260 participants and fully enroll 60 participants in this study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

12. What are the possible discomforts and risks from taking part in this Research Study?

The smart watches
In general, the physical risks of wearing the smart watch and the activity monitor are the same as wearing a regular watch. You might experience redness or slight abrasion if you are unfamiliar with wearing a watch. A study team member can help you adjust the band if the watch is too loose or tight on your wrist. You may be distracted by the prompts on the smartwatch. Do not respond to prompts while driving, walking, or doing tasks that require your attention. You may ignore them and answer them later.

Questionnaires about your health and lifestyle
Some participants may feel uncomfortable with the number or detail of questions we ask about your health and lifestyle. You are not required to answer any question which makes you uncomfortable. However, if we are unable to obtain sufficient information to assess enrollment criteria and satisfy our primary study objectives, then you might not be eligible to continue in the study.

Risks of physical function testing
There is a risk of falling during the physical tests. Falls can lead to injuries ranging

from minor to serious. Other injuries could also occur, such as damage to joints and muscles (for example, spraining an ankle). It is also possible that participants could experience fatigue, soreness, and/or discomfort due to physical activity during this study. These are unlikely to be worse than what you would experience due to increased physical activity outside of the study. Some types of discomfort are normal responses to exercise and most discomfort will generally disappear within a matter of days.

Risks measuring your location and community mobility
We will collect global positioning system (GPS) location information. This data is the same as used on smartphones to get directions to a location and electronic maps. There is a very small risk that GPS data could be intercepted and would allow others to know where you wore the watch. However, this data will not directly reveal your identity.

Risks associated with blood pressure measurement.
The risks of placing a blood pressure cuff on your arms include pinching or slight bruising. To minimize these risks, study staff are trained to appropriately administer blood pressure tests.

This Research Study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform one of the Research Team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by university policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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.

UF IRB-01 Approved

13a. What are the potential benefits to you for taking part in this Research Study?

If you are selected to be in Group 1, your answers on the smartwatch and information from watch sensors may inform your doctor and their team about your symptoms. This information might be helpful to manage your care after surgery. You might also experience some indirect benefits from your participation. The smartwatch may detect a fall automatically and ask if you had a fall. A yes response will prompt more questions about if your need emergency services. If you don't respond, emergency services will be called by the smartwatch. As a personal smartwatch, you may use other functions that you feel are beneficial to your health (e.g. heart rate, blood oxygenation, monitoring steps) or convenience (e.g. timers, stopwatch, reminders). You will be asked to return the smartwatch at the completion of your enrollment.

13b. How could others possibly benefit from this Research Study?

The findings from the study will help doctors understand if regular information about patient symptoms is helpful for better and faster recovery after surgery.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

14. What other choices do you have if you do not want to be in this study?

If you do not want to be in this study, do not sign this form. If you have already signed this form and do not want to be in this study, please notify the Principal Investigator listed in question 3 above. If you do not want to be in this study, the alternative choice is simply to not participate.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this research study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team

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may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

15b. Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from this Research Study without your consent. The most commons reasons are:

- The Principal Investigator feels that continuation could be harmful to you.
- You do not qualify to be in the study because you do not meet the study requirements. Ask the Principal Investigator if you would like more information.
- There is a change in your health that prohibits your further participation.
- You are unable or unwilling to follow the study procedures.
- You had a lot of trouble using the smartwatch that caused you frustration.
- Other reasons affecting successful administration of the research project.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

There is no fee for participating, but there may be incidental costs associated with traveling to the study site (e.g., cost of gas). There will be no additional costs to you or your health plan due to your participation in this study. There are no expected protocol-required items, services, or procedures to generate any charges at UF Health. However, if you feel you have received a bill related to this study, please contact the Principal Investigator.

17. Will you be paid for taking part in this Research Study?

If you are enrolled in the study, you will be paid $100 after the study.

Participants will receive a total of $100 for completing the study. You will receive $50 for completing your first visit and another $50 when completing your post-surgery visit approximately 30 days after your surgery. You may be compensated $25/visit more if you are asked to attend any unscheduled visits.

Participants who travel more than 20 miles one-way to our research site (more than 40 miles round trip) will receive an additional $20 for each visit to defray the cost of travel.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information (including

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your name, address, date of birth, and SSN) is protected. Access to the HSP Program site is limited to certain staff with an assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity. If you have any problems regarding your payment, contact the study coordinator.

18. What if you are injured while in this Research Study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists, and psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the Research Team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this Research Study

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SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this Research Study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization	Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use, and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing	Date

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Consent To Collect And Share Your Data For Future Research

As part of the research project “ROAMM-EHR: Pilot Trial of a Real-Time Symptom Surveillance System for Post-Discharge Surgical Patients”, Dr. Todd Manini and his research team is are seeking your consent to share your research data.

Reason for Storing Your Data:

This research study is collecting data from you. We would like to make your data available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Our goal is to make more research possible. We plan to keep your data indefinitely.

Your data may be shared with researchers around the world. However, the decision to share your data is controlled by the University of Florida. To get your data, future researchers must seek approval from the University of Florida

Any researcher using your shared data must agree not to try to identify you.

We will protect the confidentiality of your information to the extent possible. Your data will be coded to protect your identity before they are shared with other researchers. Researchers at the University of Florida will have a code key that can be used to link to your identifying information. The code key will be securely stored.

Do I have an option to allow you to share my research data?

It is your choice whether or not to let researchers share your data for research in the future. If you say “yes,” you can change your mind later. If you say “no,” you can still fully participate in this study.

If you change your mind and no longer wish to have us store or share your data, you should contact the study staff or Principal Investigator listed on the Informed Consent Form. We will do our best to honor your request and to retrieve any data that have been shared with other researchers. However, there may be times we cannot. For example, if we do not have a way to identify your data, we will not be able to retrieve them. In addition, if the data have already been used for new research, the information from that research may still be used.
Please initial next to your choice:

_____YES, use my data in other research studies

_____NO, do NOT use my data <and biospecimens> in other research studies

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Benefits to You in Storing Your Data:

You will not receive any direct benefit from sharing your data. However, sharing your data may contribute to research that could help others in the future.

Risks to You in Storing Your Data:

We will do our best to protect your data during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that unauthorized people might access your data. In either case, we cannot reduce the risk to zero.

Do You Agree to Have Your Research Data Shared?

Please review statement below and initial by your choice:

I agree to have research data shared as described in this document.

Initials _____ YES Initials _____ NO