STeP IT UP CF: Stimulating ImProved Health and Well-being in Cystic Fibrosis

Informed Consent Form, V1.1, Approved 28Mar2020

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EFFECTIVE

3/28/2020

MCW/FH IRB

Medical College of Wisconsin and Froedtert Hospital
INTRODUCTION TO THE INFORMED CONSENT

Name of Subject: _____

STeP IT UP CF: Stimulating Improved Health and Wellbeing in Cystic Fibrosis Using Integration of Fitness Technology and Port CF

Dr. Rose Franco
Pulmonary, Critical Care and Sleep Medicine
(414) 955-7040
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee WI 53226

You are invited to take part in this research. You can decide whether to take part in this project or not. You are free to say yes or no. If there is anything that you do not understand, please ask questions.

Definitions

FITBIT – A wearable device, similar to a wrist watch, that measures a person's activity and sleep levels.

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Purpose

This project is being done to determine if collecting data from a wearable device will assist care providers and patients with care of issues regarding cystic fibrosis.

Length

- You will be in this research project for at least 3 months, but possibly as long as 5 months.

Procedures *or* Activities

List of visits:

- Visit 1
  - Total Number: 1
  - Total Time: 60-90 minutes
- Visit 2
  - Total Number: 1
  - Total Time: 30 minutes
- Phone call visits
  - Total Number: 2
  - Total Time: 10 minutes each

Procedures/Activities that will occur at various visits:

Invasive Activities
- None

Non-invasive Activities
- Questionnaires, wearing of a Fitbit activity tracker

Risks

This is a brief list of the most commonly seen side effects/risks The ***full consent form*** after this introduction contains a more complete list of potential research risks.

Intervention risks:

- Wearing of Fitbit device
- Questionnaires

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Benefits

This project may not help you, but we hope the information from this project will help us provide better health services for patients with cystic fibrosis.

My Other Options

You do not have to join this project. You are free to say yes or no.

- Whether or not you join this project, you are free to seek services from this or other agencies.
- Whether or not you join this project, your usual medical services will not change.

If you have more questions about this project at any time, you can call Dr. Rose Franco at (414) 955-7040.

If you have questions about your rights as a participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

CONSENT TO PARTICIPATE IN RESEARCH

A1. INTRODUCTION – WHY ARE WE ASKING YOU TO PARTICIPATE?

You are being invited to participate in this research because you have been diagnosed with cystic fibrosis.

A total of about 21 people are expected to participate in this research at the Medical College of Wisconsin/Froedtert Hospital.

The Director of the project is Rose Franco, MD in the Pulmonary, Critical Care and Sleep Medicine. A research team works with Dr. Franco. You can ask who these people are.

The Cystic Fibrosis Foundation is funding this research.

A2. DO I HAVE TO PARTICIPATE?

You can decide whether to take part in this research or not. You are free to say yes or no. If you say no, your regular medical care will not change. Even if you join this project, you do not have to stay in it. You may stop at any time.

A3. WHY IS THIS PROJECT BEING DONE?

The purpose of this project is to evaluate how fitness technology may assist in helping anticipate CF lung health issues, issues with CF related diabetes control and measure a patient's general well-being.

This study will also compare the information from the fitness tracker to the data from the Cystic Fibrosis Foundation's database, Port CF. Patient identifiers which may include patient initials, date of birth and Port CF identification number will be collected for use as part of this study.

B1. WHAT WILL HAPPEN IF I PARTICIPATE?

All subjects will be consented to participate in this observational study for a minimum of 3 months and study visits will coincide with their standard of care clinic visit schedule. There will be a minimum of 2 clinical visits and 2 phone call visits once the subject has consented to the study. This visit schedule was selected to coincide with current care schedules.

Study visit schedule:

Study visit	Time period/Description	Duration
Visit 1	At a standard of care visit, this will be the visit that a subject will consent to the study, the Fitbit device will be set up and instruction given to the subject about how to use the Fitbit.	60-90 minutes
Phone call 1	1 week after Visit 1 – this call will be to address any issues with the data	10 minutes

	collection of the Fitbit or use of the study diary	
Phone call 2	1 month after Visit 1 – this call will be to address any issues with the data collection of the Fitbit or use of the study diary	10 minutes
Visit 2	Approximately 2-5 months after Visit 1. This will coincide with the subject's next routinely scheduled standard of care clinic visit.	30 minutes
Optional visits	To take place during any sick visits to clinic the subject would have during the study period.	10 minutes

At Visit 1, all consented subjects will be provided a Fitbit Inspire HR and shown the proper use and care of the tracker. The research coordinator will confirm the subject's ability to upload data from the device to their study Fitbit account (deidentified) under direct observation. The subjects will also receive instruction in how to document their activity and sleep in the diary app associated with their Fitbit. All subjects will have access to instructional videos and a help desk through the Fitbit resource center as well. The research coordinator will monitor the study database for the duration of the study and contact the patient via their preferred method of contact with encouragement to consistently upload data if needed.

During Visit 1 and Visit 2, subjects will complete a general quality of life in CF survey (CFQ-R) and a sleep quality index-Pittsburgh Sleep Quality Index (PQSI) survey.

To provide up to date and accurate data from the device, subjects will need to sync their device at least every 5 days to store their activity information appropriately into the study database. In addition, the Fitbit app and website have additional programs including a diary where subjects can document their exercise, activity and even sleep habits. Whenever possible the subject will document their activity through this app to provide validation of the data collected by the sensors.

The study coordinator will confirm Fitbit uploads with the subject by comparison of the data entered in the patient activity/sleep diary entry to the data from the Fitbit during the phone call visits with the subject.

A database used for collecting the Fitbit data will only be given assigned subject codes to prevent sharing of identifiable subject information. To further secure patient privacy, all subjects will have a study email account set up to tie to the trackers during the study.

If the Fitbit stops working, the subject should contact the study coordinator to arrange for a replacement Fitbit. Fitbits that are lost will not be replaced.

B2. HOW LONG WILL I BE IN THE PROJECT?

You will be in this research project for about 3-5 months.

B3. CAN I STOP BEING IN THE PROJECT?

You may stop at any time. If you decide to leave the project, please let the research team know.

The research doctor may stop your participation in the project at any time for any reason without your consent. She will tell you if this happens.

C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE PROJECT?

We watch everyone in the project for unexpected problems. **You need to tell the research doctor or a member of the research team immediately if you experience any problems.**

Questionnaires: You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately.

Fitbit: You could develop skin irritation from wearing the Fitbit. If this happens, please contact the study team for further direction and treatment. There is also a potential for psychological risks as you may feel overwhelmed or confused about how to use the Fitbit. Training on use of the Fitbit will be provided.

Another risk may be loss of confidentiality. Every effort will be made to keep your research records confidential but we cannot guarantee it. Depending on the kind of information being collected, if your research information were accidentally seen, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the project director about whether this could apply to you.

C3. ARE THERE ANY BENEFITS TO TAKING PART IN THE PROJECT?

This project will not help you, but we hope the information from this project will help us develop better health services for those with cystic fibrosis.

D1. ARE THERE ANY COSTS TO BEING IN THE PROJECT?

There are no costs to you for any of the visits or services you receive in this project. If you have questions regarding costs, please contact Dr. Rose Franco.

D2. WILL I BE PAID FOR PARTICIPATING IN THE PROJECT?

You will receive a $60.00 gift card after each upload of 20% of your FitBit data during your participation in the study, up to a maximum total payment of $300.00. You will also be able to keep the Fitbit after your participation in the study is complete.

D3. WHAT OTHER HEALTHCARE CHOICES DO I HAVE?

You do not have to join this project. You are free to say yes or no.

Whether or not you join this project, your usual medical services will not change

D4. WILL I BE GIVEN NEW INFORMATION ABOUT THE STUDY?
If we learn any important new information that might change your mind about being in the study, we will tell you about it right away. You can then decide if you want to stay in the study.

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE PROJECT?

- If you have more questions about this project at any time, you can call Dr. Rose Franco at (414) 955-7040.
- If you have questions about your rights as a research participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this project?

To be in this research project, the research team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the project. This information may come from questions we ask, forms we ask you to fill out, or your medical record, as described below. We will only collect and use information needed for the project.

The protected health information (PHI) originates from services you will or have received at one or more of the following locations: the Medical College of Wisconsin (MCW); BloodCenter of Wisconsin (BCW); Children's Hospital of Wisconsin (CHW); any Froedtert Health Affiliate-Froedtert Memorial Lutheran Hospital (FMLH), Inc.; Community Memorial Hospital (CMH) Menomonee Falls, Inc.; St. Joseph's Community Hospital (SJH) West Bend, Inc.; Froedtert & The Medical College of Wisconsin Community Physicians Clinics, Inc. (FMCWCP); the West Bend Surgery Center, LLC; and the Froedtert Surgery Center, LLC.

The health information we will collect and use for this project is:

- Health information collected during this project, such as, questionnaires
- Medical records dating from when you join this project until you complete the project.
- Activity information from the Fitbit activity tracker and online subject diary
- Medical history data from the Port CF Database

E2. Who will see the health information collected for this project?

The only people allowed to handle your health information are those on the research team at MCW/Froedtert Hospital, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.

If the costs of any necessary emergency medical treatment in the event of a research-related injury are billed to your health insurance, your health information may need to be disclosed to the insurer for billing purposes.

The research team may share your information with people who are not part of the research team because they planned, pay for, or work with us on this project. The federal Privacy Rule may no longer protect your health information once it leaves MCW/Froedtert Hospital. For this project, we plan to share information with those doctors, researchers or government representatives working with us on this project at the institutions or companies listed here:

Cystic Fibrosis Foundation/Therapeutics Development Network – Seattle, WA

We may record your research information, including results of tests, procedures or questionnaires done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record. As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law.

We will not use your personal health information for a different project without your permission or the permission of a hospital research review board (IRB). Once all personal identification is removed from your health information, the information may be used for future research or distributed to another investigator for future research without additional informed consent from you or your legally authorized representative. The information might also be used or released for other purposes without asking you. Results of the project may be presented in public talks or written articles, but no information will be presented that identifies you.

E3. What are the risks of sharing this health information?

One risk of taking part in a research project is that more people will handle your personal health information collected for this project. The research team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. Depending on the kind of information being collected, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the research doctor about whether this could apply to you.

E4. How long will you keep the health information for this project?

If you sign this form, we plan to keep your information for 10 years after the research project ends in case we need to check it again for this project.

E5. Can I cancel my permission to share this health information?

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to Dr. Rose Franco at *8701 W Watertown Plank Road, Milwaukee, WI 53226*. The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the project. We may still use the information we have already collected.

CONSENT TO PARTICIPATE

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
- The project's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the research team use and share the health information and other information gathered for this project.
- I voluntarily agree to participate in this research project. I agree to follow the procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Date or Date & Time: Time is optional to include; if included, must be completed by each signer.

Subject's Name *please print*	**Subject's Signature**	**Date** OR **Date/Time**

Name of Legally Authorized Representative *please print*	**Signature of Legally Authorized Representative**	**Date**
Name of Subject *please print*	***Relationship to Subject*** *(e.g. Court-appointed guardian, healthcare power of attorney, next of kin, etc.)*	

*** Name of person discussing/ obtaining consent** *please print*	**Signature of person discussing/obtaining consent**	**Date**

** A member of the research team trained and authorized by the Principal Investigator to act on her/his behalf in obtaining informed consent according to the protocol. The Principal Investigator is responsible and accountable for the research project.*