Consent Fact Sheet

Study Title: The Role of Wearable Technology in Cardiothoracic Surgery: Predicting and Detecting Postoperative Complications.

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Principal Investigator: Dr. Chi-Fu Jeffrey Yang, MD

Taking part in this research study is up to you and completely voluntary. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get or any benefits you have the right to receive at Partners now or in the future. Please read this form and ask any questions that you may have before agreeing to participate.

Why is this research being done and why are we asking you to participate?
This is a research study that is being done because we want to learn more about the use of personal wearable devices (a Fitbit or Apple Watch) to measure things that have to do with the body (such as: heart-rate, steps taken, sleep cycles, and calories expended) and link that information with how you are recovering from surgery. The goal is to better predict and understand physiologic processes that are associated with complications that occur after surgery.

How did we identify you for participation?
Your surgeon mentioned this study to you during your previous visit and you agreed to learn more about the study, or you have signed up to receive direct contact from researchers in the MGB healthcare system.

Who will participate in this research?
We hope to recruit up to 1000 adults that are having any surgery in their chest (cardiothoracic surgery) at Massachusetts General Hospital (MGH).

What will happen if you take part in this research study?
If you agree to participate in this research, we would ask of you the following:
• Allow us to collect **demographic information** and **pertinent health information from your electronic medical record**. **This will include records from emergency room visits and inpatient visits**.
• You will either be given a wearable device, such as a Fitbit or iWatch, or if you own a Fitbit or Apple Watch, you may agree to share your data with us.
• We ask you to **wear the device every day, for up to 24 hours per day, over the course of approximately 4 months**. You can remove the device for part of each day as needed for charging or for comfort.
•You will be asked to download a smartphone application and may be lent accessories to collect other health information, such as a pulse oximeter that you would wear on your finger to collect the amount of oxygen in your blood.
• You will **begin wearing the device up to 3 weeks before your surgery** so we can get a baseline of your normal activities and behaviors.
• **The device will be removed during your actual surgery** and replaced as soon once the surgery is finished.
• You will **wear the device for around 90 days after your surgery** in the same way you did as before your surgery.
• You may be asked to fill out a short survey before and after your operation **as well as a 5-minute daily symptom** survey that you can complete on your phone.
• **If you have a complication from your surgery, you may be asked to fill out a 5-10-minute survey** regarding your symptoms that you can complete on your phone.
• **If you are seen in the emergency department or are readmitted to the hospital within the 90-day period after your surgery the study staff will be notified** through the electronic medical record.
• After completion of the 4-month period, **you will return the device and any accessories lent for the study**, and we will reset the device(s), so we no longer have access to your data. If you used your own device, you will reset the device to an email and password of your choice, so we are no longer able to access your data.

• ***HeartBit:*** The mobile application HeartBit was developed by our research team and is a tool that collects survey responses. Your survey answers will be accessed directly by CWRU through this application, it does not allow for the collection of any personal or identifying information.
• ***Data Analysis:*** You will upload your wearable device information and survey responses to secure platforms that will be accessed by investigators at MGH and at Case Western Reserve University (CWRU) for data analysis. No identifying information will be used or shared for data analysis.
•***End-user license agreements***: you may have to accept end-user license agreements if you are not already using the device or application. These are legal agreements between the developer (such as Apple, Fitbit, Samsung) and the consumer/user that explain the rights and restriction that apply to the software. These are agreements that are signed for everyday use of your cell phone whenever you install or update your phone or applications. In general, these agreements protect the developer's rights to the content that consumers are using, and users waive their right to freely take the intellectual property of the developer.
• ***Lost Device:*** if you happen to lose a device provided by the study team, please notify us immediately. Replacement of the device will be at the discretion of the research team and the availability of additional devices.

How will my information be protected?
The records of this research will be kept confidential. Any time information is collected, there is a potential risk for loss of confidentiality, but every effort will be made to keep your information confidential. In any sort of report, we might publish, we will not include any information that will make it possible to identify a participant. **All information from the wearable device that is collected and uploaded to secure platforms at CWRU will not directly identify you.** Investigators at MGH will collect the serial device number with your name and electronic medical record to link you to your identifiable information and this will not be shared. **All of your identifiable information will be kept in a separate secure location from the research data on MGH networks.** Your identifiable information will never be shared with anyone outside of the study staff and research regulatory agencies.

What are the risks of the study?
Taking part in this research study has minor risks but you should consider them carefully. Important risks and possible discomforts to know about include: **a risk of a breach of confidentiality** of your medical information or device information. There is **a possible low risk, of a skin reaction to the bands supplied by the wearable device manufacturers**. ***If you experience any discomfort physically or emotionally that you think is due to the device, please stop wearing it immediately and let the research team know.***

How may we use and share your health information for other research?
Your information that is not identifiable may be used for future research studies or distributed to another investigator for analysis or future research studies without your additional informed consent. However, it won't be possible to link the information or samples back to you.

Will you get the results of this research study?
Your surgical provider maybe contacted based off of your device results and survey responses, if this happens, we will let you know. In general, you should **not** expect to get information about the results of the research study or the results of your individual participation in the research study.

If you have questions or concerns about this research who can you contact?
Dr. Chi-Fu Jeffrey Yang, MD is the person in charge of this research study. You can call him at **617-726-5200, Monday-Friday from 9am-5pm or by email at cjyang@mgh.harvard.edu.** If you'd like to speak to someone **not** directly involved in this research about your rights as a research subject, or any concerns or complaints you may have, contact the Partners Human Research Committee at **(857) 282-1900.**

*****_We are required by the Health Insurance Portability and Accountability Act (HIPAA) to protect the privacy of health information obtained for research. This is an abbreviated notice and does not describe all details of this requirement. During this study, identifiable information about you or your health will be collected and shared with the researchers conducting the research. In general, under federal law, identifiable health information is private. However, there are exceptions to this rule. In some cases, others may see your identifiable health information for purposes of research oversight, quality control, public health and safety, or law enforcement. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy._