University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: December 7, 2016
IRB Study # 16-3306
Title of Study: The cardiac rehab transition: pilot intervention
Principal Investigator: Kelly Evenson
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Funding Source and/or Sponsor: N/A

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is an initial step in understanding whether or not wearing an activity tracker to monitor your physical activity is associated with better maintenance of physical activity following cardiac rehabilitation discharge. You are being asked to be in the study because you are attending a cardiac rehabilitation program.

How many people will take part in this study?
A total of approximately 5 people will take part in this study.

How long will your part in this study last?
You will be asked to wear the activity tracker until 8 weeks following cardiac rehabilitation discharge. We will meet with you at the beginning and end of the study. The initial visit will take 1 hour and the final visit will take 30 minutes.

What will happen if you take part in the study?
We will meet with you at your cardiac rehabilitation program, along with some or all of the other study participants if they are available. You will be asked to complete a survey. The staff will help you set-up the activity tracker account and load it onto your mobile phone. We will ask you to wear the activity tracker every day; you can take it off at night.

At around 8 weeks after cardiac rehabilitation discharge, we will meet with you and ask you to complete another survey. That meeting will indicate the end your study participation.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may be that you are able to better maintain your physical activity following cardiac rehabilitation compared to patients who are not using an activity tracker.

What are the possible risks or discomforts involved from being in this study?
You may find that the activity tracker is uncomfortable to wear on your wrist. You should report any problems, such as these, to the researcher.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
Participants will not be identified in any report or publication about this study. The survey and activity tracker data will be stored on secured password protected computers. Only the study team will have access to the file that links your name to the research data. That file will be destroyed when the 5 participants finish the study.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have failed to follow instructions, or because the entire study has been stopped. If you withdraw from the study or if the investigators ask you to stop participation, we will ask you to return the activity tracker back to the research team.

Will you receive anything for being in this study?
You will be allowed to keep the activity tracker at the conclusion of your participation in the study.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

Who is sponsoring this study?
This research is funded by the NC Translational and Clinical Sciences (TraCS) Institute at the UNC–Chapel Hill. Both UNC-Chapel Hill and RTI International are involved in this study. This means that the research is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Signature of Research Participant Date

_____
Printed Name of Research Participant

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent