COMIRB
APPROVED
For Use
14-Jul-2026

Consent and Authorization Form

Principal Investigators: Jennifer Portz, PhD, MSW and Christopher Knoepke, PhD, MSW

COMIRB No: 24-0628

Version Date: 6/15/2026

Study Title: Commercially Available Fitness mHealth for Cardiac Rehabilitation among Individuals Recovering from Transcatheter Aortic Valve Replacement

---

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study aims to evaluate the efficacy of CardioHeartConnect on physical activity, functional capacity, quality of life, and cardiovascular health status among patients recovering from Transcatheter Aortic Valve Replacement (TAVR). The study will be conducted through a randomized controlled trial involving 200 TAVR patients recruited from the UCHealth Structural Heart & Valve Clinic. You are being asked to be in this research study because you are recovering from TAVR and are clinically appropriate for cardiac rehabilitation.

What happens if I join this study?

If you join the study, you will complete a survey about your health. We will help you log in and use all the study technologies. Additionally, you will be provided with a smartwatch to wear for seven days in a row. You will be asked to share your watch data with the study team via Ortus and/or CardioHeartConnect platforms. After wearing the smartwatch for seven days, the research team will contact you to verify that your survey is complete and that your smartwatch data is uploaded to the study platform. You will then be randomly assigned (50/50 chance or a flip of a coin) to either the CardioHeartConnect group or the CardioHeartEd group. The research team will provide you with a tutorial on how to use the study platform depending on your group assignment.

If you are assigned to the CardioHeartConnect group, the research assistant will help you download the Peloton app, a commercially available fitness app. You will engage with cardiac rehabilitation-related Peloton modules focusing on walking, strength, low-intensity cardiovascular exercises, yoga and pilates, and stretching for 8 weeks. Each weekday, you will complete two Peloton modules totaling 10-25 minutes while wearing the smartwatch, with Peloton modules progressing over time. You will be prompted by the study platform to complete these modules daily. If you are assigned to the

CardioHeartEd group, you will have access to the smartwatch. You will engage with cardiac rehabilitation-related resources that will be sent to you weekly.

After 8 weeks and 12 months, the research team will follow up with you to complete the health survey again. You will keep the smartwatch for the full 12 months of the study. At the 12-month follow-up, the research team will contact you to collect the smartwatch. If you choose to wear the smartwatch at any time between the end of the 7-day baseline wear and the 12-month follow-up, the device will continue to collect passive activity data. The study team will have access to this data; however, it will be used for research purposes only. The study team will not monitor the data in real time and will not use it to detect or respond to falls, heart rate changes, emergencies, or any other health concerns.

As part of your participation in the study, you must agree to the terms and conditions of using the Peloton app. A full copy is attached for your review and records. In summary, the research team will manage membership payment obligations and cancellation procedures with Peloton. By using the Peloton App One subscription, you agree to use it for personal, non-commercial purposes only. You must be at least 13 years old to create an account. Your activity and any content you share on the app may be used by Peloton in accordance with their policies. You are responsible for your own safety while using the app, and Peloton is not liable for any injuries.

What are the possible discomforts or risks?

Potential discomforts or risks you may experience include:

(1) Falling, tripping or injury during the CardioHeartConnect intervention.

(2) Psychological discomfort when filling out the health survey, particularly since the survey is interested in your quality of life and aspects of mental health, such as anxiety and depression. You may feel uncomfortable answering some questions.

(3) Increased pain or other symptoms from increased physical activity. It is common to experience some temporary pain when starting a new exercise program.

(4) Potential loss of confidentiality due to sharing features on the Peloton app (i.e. Peloton friends, sharing exercise modules, sharing completed module results, etc.).

The research team has established protocols to minimize risks, including falling or injury during the intervention, psychological discomfort, increased pain from physical activity, and potential loss of confidentiality. Emergency contact information will be collected, and emergency protocols are in place to address any adverse events promptly. The study may include risks that are unknown at this time.

What are the possible benefits of the study?

While we are unsure if participants will experience benefits from the study, participation may improve access to cardiac rehabilitation options and promote physical activity among TAVR patients. If successful, CardioHeartConnect could serve as a model for enhancing cardiovascular health and quality of life in this population.

Are there alternative treatments?

You may choose to participate in cardiac rehabilitation alone or in conjunction with CardioHeartConnect or CardioHeartEd.

Who is paying for this study?

This study is funded by the National Heart, Lung, and Blood Institute (NHLBI).

Will I be paid for being in the study? Will I have to pay for anything?

You will be compensated a $25 gift card for completing each survey, one at 8-week follow up and another at 12-month follow-up with a possible total of $50. It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?

The study investigators & research team may decide to stop your participation without your permission if they think that taking part in this study may cause you harm, or for any other reason. The study sponsor may also choose to stop the study at any time.

What happens if I am injured or hurt during the study?

The University has no plan to pay for a physical or psychological injury resulting from this study. If you are injured or hurt during this study, you may call the study principal investigators Drs. Jennifer Portz and Chris Knoepke at 303-724-8856 or by emailing the study team at CardioHeartConnect@cuanschutz.edu.

Who do I call if I have questions?

The researchers carrying out this study are Drs. Jennifer Portz and Chris Knoepke. You may ask any questions you have now with the study research team. If you have questions later, you may call the researchers at 303-724-6170.

You may have questions about your rights as someone in this study. You can call Drs. Portz and Knoepke with questions. You can also call the Colorado Multiple Institutional Review Board (COMIRB), the organization who oversees this study, at 303-724-1055.

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and the health systems it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus
- University of Colorado Health

We cannot do this study without your permission to see, use, and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate health systems may not be covered by this promise.

We will do everything we can to keep your records a secret, however, it cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigators, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end, and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Jennifer Dickman Portz, PhD, MSW
Assistant Professor
General Internal Medicine
University of Colorado Anschutz
Mailstop B119
13001 East 17th Place
Aurora, Colorado 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, including:

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study principal investigators and the rest of the study team.
- NHLBI, who is the institution paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the study investigators.

The investigator and/or research team will also make collected health information about you available to:

- ORTUS-iHealth, a platform that links watch data to the study team
- CardioHeartConnect by the CU mHealth Impact Lab, a more recent platform that links watch data to the study team
- Peloton and its entities, the commercially available fitness program

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)

- Portions of my previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records
- If you choose to wear the smartwatch at any point after the initial 7-day wear period and before the 12-month follow-up, the device will continue collecting passive activity data. This data will be accessible to the study team and used only for research. It will not be monitored for falls, heart rate abnormalities, emergencies, or real-time safety concerns.

By using the Peloton app you grant Peloton a license to use that content, including:

- Device types, IP address, browser types
- App activity (i.e. which class you take, duration, interactions, etc.)
- Data from connected devices (Apple or Garmin Watch)
- Optional data you enter (e.g. weight, fitness goals, etc.)
- Anything you post or share in the Peloton or study platform apps (Ortus or CardioHeartConnect mHealth Lab platforms) (e.g. photos, tags, comments, etc.)

What happens to the Data that are collected in this study?

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The data are given by you to the investigators for this research study and so no longer belong to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.
- Any additional data passively collected from the smartwatch between the end of the 7-day wear and the 12-month follow-up will also be included in the research dataset. This data is not monitored in real time and is not used for clinical or safety purposes.

Agreement to be in this study and use my data

I have read this consent form about the study or it was read to me by a member of the research team. I understand the possible risks and benefits of this study. I understand and authorize the access, use, and disclosure of my information as stated in this form. I know that participating in this study is voluntary. You will get a signed and dated copy of this consent form.

Signature:

Date:

Print Name: _____

Consent form explained by:

Signature:

Date:

Print Name: _____