	CONSENT TO PARTICIPATE IN A RESEARCH STUDY (HFH IRB form rev: 02/2012)	DATE: MRN: NAME:

APPROVED **24-June-2022** **INSTITUTIONAL REVIEW BOARD**	**PROJECT TITLE:** **The improving ATTENDance to Cardiac Rehabilitation (iATTEND) Trial**

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1. WHY IS THIS RESEARCH BEING DONE?

You have been asked to take part in a research study because you have a qualifying diagnosis (heart failure, myocardial infarction, valve repair or replacement, angina, coronary arthrosclerosis, cardiomyopathy, stent, coronary artery bypass graft, left ventricle assistant device, and/or heart transplant) and a referral for cardiac rehabilitation from your doctor. The purpose of this research study is to assess the effect of a home-based cardiac rehabilitation combined with a center based cardiac rehabilitation compared to traditional center based only cardiac rehabilitation.

There will be approximately 300 people in this research study at Henry Ford Health System (HFHS).

This study is sponsored by National Institute of Health (NIH). This means that the sponsor is compensating HFHS for the costs of carrying out this research.

As part of this study, you may have a procedure called Cardiopulmonary Exercise Test (CPX). This procedure is not experimental. As part of this study, you will also participate in either a combined center based and home based cardiac rehabilitation (HYCR) or center only based cardiac rehabilitation (CBCR) program. These programs are not experimental.

The purpose of this study is to optimize the utilization of cardiac rehabilitation (CR). Currently many patients that participate in CR attend fewer sessions than prescribed. This study aims to increase attendance to CR by integrating a home based cardiac rehabilitation program (delivered via telemedicine) with existing center based cardiac rehabilitation programs.

2. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

Your participation in this study will last a total of 9-12 months. As part of this study, you will have 4-39 visits to the clinic. At visit 1, visit 38 (10 days after completing cardiac rehabilitation) and visit 39 (6 months after completing cardiac rehabilitation) you will have the following procedures:
extra and experimental: none
extra and not experimental:

- Six minute walk test: Walk on a flat surface (hallway) for six minutes covering as much ground as you can comfortably. You may slow down or stop to rest as needed. This will take about 10-15 minutes total to complete.
- Cardiopulmonary Exercise Test (CPX): This test is also known as a stress test, in which you will walk on a treadmill at an increasing intensity until you become too tired to continue. You will be encouraged to give your best effort possible. During the test your heart will be monitored by electrocardiogram (EKG). The air you breathe will be monitored through a mouthpiece that is similar to a snorkel. Both instruments are commonly used and proven safe. Your heart rate and blood pressure will also be monitored during exercise. This test will last approximately 60 minutes, but the exercise portion of this test will only last between 6 and 12 minutes.
- EuroQUAL and Dartmouth COOP Questionnaires: Paper quality of life surveys to assess your perceptions of the state of your health. These will take about 10 minutes to complete.
- International Physical Activity Questionnaire: Paper survey to assess your daily physical activity and sedentary behaviors. This will take about 10 minutes to complete.

At the cardiac rehabilitation visits 2-37 you will have the following procedures:
extra and experimental: none
extra and not experimental:

- You will have 6 months to participate in cardiac rehabilitation (CR) and complete the scheduled 36 CR sessions. There will be two groups in the study. The group you are assigned to will be chosen by chance (like flipping a coin). You will either be assigned to the center based cardiac rehabilitation group (CBCR) or the combined center based cardiac rehabilitation and home based cardiac rehabilitation group (HYCR). The home based cardiac rehabilitation sessions will be delivered via telemedicine. A free video application (app) will be loaded on to your smart phone or tablet (or that of a “willing to assist” friend or family member).
- If you are chosen for the HYCR, you will complete at least 1 but no more than 12 sessions at one of Henry Ford Hospital’s cardiac rehabilitation sites. The remaining 24-35 sessions will be home based via telemedicine. The number of CBCR sessions will be tailored to your individual needs. You will also be asked to watch 28, 7-15 minute video education lectures.

If you are chosen for the CBCR group, you will complete all 36 (2-3 sessions per week) CR sessions at one of Henry Ford Hospital’s cardiac rehabilitation sites. You will also be asked to attend 8, one hour group education lectures. This is the current standard of care for cardiac rehabilitation.

3. WHAT ARE THE RISKS OF THE STUDY?

You should tell the person obtaining your consent about any other medical research studies you are involved in right now. While you are in the study, you are at risk for the following side effects:

- Likely: Temporary shortness of breath or fatigue associated with performing exercise or exercise testing. These symptoms typically resolve within minutes after exercise has stopped.
- Less Likely: Blisters, sprains, strains, muscle fatigue and muscle soreness.
- Rare but serious:
  - Abnormal blood pressure or heart rate, dizziness, fainting associated with exercise.
  - The overall incidence of a serious cardiac event (heart attack or death) during maximal exercise testing is very low at 4 per 10,000 tests (.04%). In patients with heart failure, up to 2 percent of patients undergoing an exercise test have had a serious abnormal heart rhythm, but none of these episodes caused any immediate death during the exercise testing. Personnel trained to manage such complications will supervise your exercise test.
  - The rate of complications for all participants in cardiac rehabilitation is very low. Only one major event (heart attack, sudden death) per 50,000 to 120,000 patient-hours of exercise.
  - Very rarely there could be breach of confidentiality of your health information. The research team will be the only people with access to your health information and it will kept in a locked file. All efforts will be made to keep this information confidential

There may be additional risks or discomforts that are not known at this time.

4. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

The benefits of participating in this study may include: improved fitness level, quality of life, and symptoms of shortness of breath or fatigue. You may not be helped by participating in this study. However, others may be helped by what is learned from this research. The benefits of CR include but are not limited to, an increase in functional capacity and quality of life, reduced re-hospitalizations, and improved survival.

5. WHAT OTHER OPTIONS ARE THERE?

You do not have to participate in this study. Your other choices may include:

- Getting treatment or care for your qualifying diagnosis (heart failure, myocardial infarction, valve repair or replacement, angina, coronary arthrosclerosis, cardiomyopathy, stent, coronary artery bypass graft,

left ventricle assistant device, and/or heart transplant) without being in a study, such as participating in traditional cardiac rehabilitation at Henry Ford Hospital's Detroit site or another location, and/or following up with your doctor.

- Taking part in another study
- Getting no treatment

Talk to your doctor about your choices before you decide if you will take part in this study.

6. WHAT ABOUT CONFIDENTIALITY?

By signing this consent form, you agree that we may collect, use and release your personal and health information for the purpose of this research study.

We may collect and use:
- Your existing medical records.
- New health information created during this study.
- Health insurance and other billing information.

We may release this information to the following people:
- The Principal Investigator and his/her associates who work on, or oversee the research activities.
- Government officials who oversee research (Food and Drug Administration).
- The research sponsor, National Institute of Health (NIH)
- Your insurance company or others responsible for paying your medical bills.
- Other researchers at other institutions participating in the research.

Once your information has been released according to this consent form, it could be released again and may no longer be protected by federal privacy regulations.

This consent form, test results, medical reports and other information about you from this study may be placed into your medical record. Generally, you are allowed to look at your medical record. During the research study, you will not be allowed to look at your research study information that is not in your medical record.

HFHS or others may publish the results of this study. No names, identifying pictures or other direct identifiers will be used in any public presentation or publication about this study unless you sign a separate consent allowing that use.

This consent to use and release your personal and health information will not expire at the end of this research study.

You do not have to sign this consent to release your medical information and may cancel it at any time. If you decide not to sign this consent or cancel your consent, you cannot participate in this study. If you notify us that you wish to stop participating in this study, we may continue to use and release the information that has already been collected. To cancel your consent, send a written and dated notice to the principal investigator at the address listed on the first page of 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.

7. WHAT IF I AM INJURED?

There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study. You are not giving up any of your legal rights by signing this consent form.

8. WHO DO I CALL WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?

Steven Keteyian, PhD, Principal Investigator, or his staff member, has explained this research study and has offered to answer any questions. If you have questions about the study procedures, or to report an injury you may contact Steven Keteyian, PhD at 313-972-1920. Medical treatment is available to you in case of an injury.

If you have questions about your rights as a research subject you may contact the Henry Ford Health System IRB Coordinator at (313) 874-4464. The IRB is a group of people who review the research to protect your rights.

9. DO I HAVE TO PARTICIPATE IN THIS STUDY?

No, your participation in this research study is voluntary. If you decide to participate, you can stop at any time. If this happens, you may be asked to return for a visit for safety reasons. You will get the same medical care from HFHS whether or not you participate in this study. There will be no penalties or loss of benefits to which you would otherwise be entitled if you choose not to participate or if you choose to stop your participation once you have started. You will be told about any significant information that is discovered that could reasonably affect your willingness to continue being in the study.

10. WHO ELSE CAN STOP MY PARTICIPATION?

The Principal Investigator, sponsor or your doctor can end your participation in the research study at any time. If this happens, you may be asked to return for a visit for safety reasons.

11. WILL IT COST ANYTHING TO PARTICIPATE?

We do not expect there to be any additional costs to you if you participate in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company. You have the right to ask what it will cost you to take part in this study.

12. WILL I BE PAID TO PARTICIPATE?

You will receive a $40 at the baseline testing visit, follow up visit 1 (completed within 10 days of completing your cardiac rehabilitation sessions), and follow up visit 2 (completed 6 months after completing your cardiac rehabilitation sessions. If you have a co-pay through your insurance for cardiac rehabilitation, those co-pays will be reimbursed. To receive reimbursement, please bring in your insurance bill or explanation of benefits to cardiac rehabilitation staff or research staff. If you do not finish the study, you will be paid for the part that you did complete.

You will receive payment via a ClinCard, which is a specially designed debit card for clinical research that works like a bank debit card. Each time you receive a payment for participation in this study, the money will be added to the card after each completed visit. The debit card system is administered by an outside company. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. In order to receive

payment, we will need to collect some information about you, including your name, address, date of birth, medical record number, social security number, and your patient study ID code. All information is stored in a secure fashion and will be deleted from our records once the study has been completed and the funds on your ClinCard have been exhausted. You may use this card at any store that accepts credit cards. You may also withdraw cash. Please be aware that there may be fees drawn against the balance of the card for cash withdrawals and inactivity. You will receive additional information on how you can use this card and any fees that may apply.

HFHS is required to report payments of $600 or more to the Internal Revenue Service (IRS). If you receive $600 or more from participating in research at HFHS during the calendar year, your compensation will be reported to the IRS and you will also receive an IRS 1099 Form.

13. CONSENT

You have read this consent form or it has been read to you. You understand what you are being asked to do. Your questions have been answered. Any technical terms you did not understand have been explained to you. You agree to be in this study. You will be given a copy of this consent form.

COMPETENT ADULT SUBJECT

Signature of Subject	Date	Time
Print Name of Subject		
Witness to Signature	Date	Time
Print Name of Person Obtaining Consent		

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