CONSENT FORM
v3

Title of this Research Study

Invitation and Summary

You are invited to be in this research study. Taking part in this research is voluntary. You do not have to take part. For the purposes of this document: "You" can refer to:

- Yourself
- The person for whom you are the Legally Authorized Representative (LAR)
- Your child under the age of 19.

"Organization" can refer to: University of Nebraska Medical Center (UNMC), Nebraska Medicine (NM), University of Nebraska at Omaha (UNO) or Children's Nebraska (CN).

Here is a summary of the purpose, methods, risks, benefits, and alternatives, to help you decide whether or not to take part in the research.

We are doing this study to learn more about patients with heart failure with preserved ejection fraction and exercise. We want to see if meeting with a coach will help these patients exercise, feel better, and change markers in their blood.

We are asking patients to stay in this study for 6 months. We will put patients in 2 groups. The chances of being selected for either group are like flipping a coin. The Gym group will get an online gym membership. The Coach group will get an online gym membership plus an online coach that they meet with once a week. All study patients will do an exercise test, have 3 blood draws, and take part in study training. They will wear an activity monitor 3 times for 7 days each, wear a heart rate monitor when they exercise, and fill out a daily exercise diary. We will also ask them questions related to their heart failure and exercise.

The risks of exercise in heart failure with preserved ejection fraction are feeling tired, muscle and joint pain, breathing problems, having irregular heartbeats or blood pressure changes, or in rare cases, death. Patients will take an exercise test to check if they are safe to exercise.

Patients may be helped by exercising, but exercise may not help everyone. Instead of being in this study, patients can choose not to be in the study. Choosing to not be in the study will not affect relationships with your care provider or Nebraska Medicine.

Why are you being asked to be in this research study?
You are being asked to be in this research study because you are an adult, 19 years of age or older, with heart failure, and you have been on the same medications for the last 30 days. If you have had a heart attack, had open-heart surgery, or received a pacemaker in the last 6 weeks, or if you have more symptoms from your heart failure, you cannot be in this study.

What is the reason for doing this research study?
We are doing this research study so we can see if having an exercise coach and access to an online exercise program helps people with heart failure to start exercising and keep exercising.

What will be done during this research study?
In this study, we will ask you to:

When you start the study, we will ask you to complete the following within 2 weeks:

1. Take an exercise test. We will set up a time for you to come to Nebraska Medicine to undergo an exercise test. During the exercise test, you will be asked to ride an exercise bicycle or walk on a treadmill while we monitor your heart, breathing, and blood pressure. A healthcare provider will be with you during the entire test and give you directions on what to do. For the first 2-3 minutes, you will be asked to sit quietly while we collect information at rest. We will begin with a 2-3-minute warm-up period before you are asked to exercise. During the exercise part of the test, we will ask you to peddle the bicycle or walk on the treadmill as best you can. The exercise part will last between 5 and 12 minutes. You can expect this visit to take between 45 and 60 minutes altogether, plus your travel time. The results of this test will help us to make sure you are safe to exercise and tell us where you should keep your heart rate while you are exercising. We will pay for this test.
2. Come to one of our outpatient labs to have your blood drawn. We will collect 5ml (1 teaspoon) of blood from you. We will help you to find a time and place to do this that works for you. We will come with you to the lab so we can take your blood for testing related to the study. We will look for proteins in your blood.
3. Answer some questions about your symptoms, how good you feel your life is, and about your heart failure. We will send you a link to a survey that will take about 30-60 minutes to answer questions related to exercise and heart failure. We will check to see if you completed this and if you didn't, we will call to help you. If you respond that you have often or always felt depressed

and/or hopeless in the past 7 days, we will refer you to your primary care provider. We will also ask you if you have any intention of hurting yourself and if you answer yes to this question, we will refer you to the Emergency Department.

4. Come to UNMC for study training. During this training, we will teach you what you need to do as part of the study. We will teach you how to use a heart rate monitor and how and when to send your data to us, how to wear an activity monitor, and how to get to exercise sessions online. We will give you a heart rate monitor and pay for 6 months of an online gym membership. At this training visit, we will ask you to walk on a flat surface for 6 minutes to see how far you can walk in that time.
5. Wear an activity monitor for 7 days. We will show you how to wear it and how to send it back to us in a prepaid envelope.
6. At the end of the study training, we will divide you into one of 2 groups for the study: the Gym group and the Coach group. Your chances of being selected for either group are similar to flipping a coin.

Participants in the Gym group will be given an online gym membership for 6 months.

Participants in the Coach group will be given an online gym membership for 6 months and an online coach for 3 months. Participants in the Coach group will meet with a coach on the internet for 30 minutes per week. This coach will be from UNMC and they will help you learn to exercise. Coaches will talk to you about problems or concerns with exercise and talk to you about goals for each week. One week per month from the beginning of Month 1 to the beginning of month 5, participants in the Coach group will meet on the internet with a coach and no more than 4 other Coach group participants to do a group exercise session. We will show you what this might look like during your training.

After training for Months 1-6, we will ask you to:

1. Wear a heart rate monitor on your wrist and chest or arm while exercising. We will provide these for you and if you continue in the study until it is over, you can keep them when the study is over. We will show you how to send us this data during your training.
2. Exercise for 150 minutes a week using our online fitness classes for the next 6 months. We will show you how to log into these classes during your training. When you exercise using our online classes, you will need to have someone in the home with you or on video over the internet to be able to see you while you are exercising. We will pay for your online fitness membership for 6 months.
3. Write in a diary about your exercise each time you exercise. We will provide a

diary for you to mark down when and how long you exercise, and how you felt during exercise. We will tell you how to send these back to us.

After 3 months in the study, we will ask you to:

1. Come to one of our outpatient labs to have your blood drawn. We will collect 5ml (1 teaspoon) of blood from you. We will help you to find a time and place to do this that is convenient for you. We will come with you to the lab so we can take your blood for testing related to the study. We will look for proteins in your blood.
2. Wear an activity monitor for 7 days. We will show you how to wear it and how to send it back to us in a prepaid envelope.
3. Answer some questions about your symptoms, how good you feel your life is, and about your heart failure. We will send you a link to a survey that will take about 30-60 minutes to answer questions related to exercise and heart failure. We will check to see if you did this and if you didn't, we will call to help you. If you respond that you have often or always felt depressed and/or hopeless in the past 7 days, we will refer you to your primary care provider. We will also ask you if you have any intention of hurting yourself and if you answer yes to this question, we will refer you to the Emergency Department.
4. We will ask you to walk on a level surface for 6 minutes to see how far you can walk in that time.

After 6 months in the study, we will ask you to:

1. Come to one of our outpatient labs to have your blood drawn. We will collect 5ml (1 teaspoon) of blood from you. We will help you to find a time and place to do this that is convenient for you. We will come with you to the lab so we can take your blood for testing related to the study. We will look for proteins in your blood.
2. Wear an activity monitor for 7 days. We will show you how to wear it and how to send it back to us in a prepaid envelope.
3. Answer some questions about your symptoms, how good you feel your life is, and about your heart failure. We will send you a link to a survey that will take about 30-60 minutes to answer questions related to exercise and heart failure. We will check to see if you did this and if you didn't, we will call to help you. If you respond that you have often or always felt depressed and/or hopeless in the past 7 days, we will refer you to your primary care provider. We will also ask you if you have any intention of hurting yourself and if you answer yes to this question, we will refer you to the Emergency Department.
4. We will ask you to walk on a level surface for 6 minutes to see how far you can walk in that time.
5. Talk to us about your experience in the study. We will interview you for no more than 30 minutes over the phone about your thoughts on being in a

research study and our exercise coaches if you had one.
We will provide you with a detailed schedule to keep track of your study visits.

There are no plans to perform any genetic tests (including whole genome sequencing) on your samples.

What are the possible risks of being in this research study?

- There are risks with exercise including having irregular heartbeats, blood pressure changes, feeling tired, feeling short of breath, and/or muscle and joint pain. There is a rare, but possible risk of death while exercising or completing exercise testing.
- There is a risk that you will experience discomfort, pain, or bruising at the site where your blood is drawn. There is also a possible risk of infection at the site of the needle puncture. The healthcare professional drawing your blood has been trained to reduce these risks as much as possible.
- There is an uncommon, but possible risk of psychological discomfort and burden that may accompany the questions we ask you. You may feel uncomfortable when answering some of the questions on the surveys or during the interview. You do not have to answer our questions and may decline to answer any of the questions or stop the interview at any time if you are uncomfortable.
- The risk of loss of confidentiality is always possible, but we will do our best to protect your data. Since a heart rate monitor is being utilized that is Bluetooth enabled and involves the internet, it is possible that private data from this monitor could be captured during transmission by people not helping with the study. We will only use your birth year so we protect your birth date, and we will set up a study email account for you that doesn't identify who you are. Although we have made these efforts, confidentiality during Internet communication procedures cannot be promised and it is possible that additional information beyond that collected for research purposes may be captured and used by others that are not part of the study or from UNMC.
- You could have other side effects that we do not know about yet.

What are the possible benefits to you?
You may feel better from exercising. You may not get any benefit from being in this research study.

What are the possible benefits to other people?
The information to be gained from this study may provide knowledge to help patients with heart failure exercise in the future

What are the alternatives to being in this research study?
Instead of being in this research study, you can choose not to take part. You can buy the heart rate monitor used in this study at a retail store.

What will being in this research study cost you?
There is no cost to you to be in this research study. Costs of the exercise test and online gym membership will be paid for by the study.

Will you be paid for being in this research study?
You will be compensated for being in this study. If you remain in the study through the final data collection at 6 months, you will be entitled to keep your heart rate monitor and chest strap or armband. If you leave the study early, we will pay you with a $20 Visa gift card for each data collection time point you complete and ask you to return your heart rate monitor and chest strap or armband in a prepaid envelope.

Who is paying for this research?
This research is being paid for by the College of Nursing of the University of Nebraska Medical Center and a research grant from the Great Plains Institutional Development Award Clinical and Translational Research (Great Plains IDeA CTR) Center awarded by the National Institute for General Medical Sciences of the National Institutes of Health.

What should you do if you are injured or have a medical problem during this research study?
Your health and safety is our main concern. If you are injured or have a medical problem because of this study call someone listed at the end of this consent form. You can get emergency medical treatment at Nebraska Medicine. You can also go to your doctor, the nearest emergency room or call 9-1-1.

We have no plans to pay for your treatment or give you any other money or compensation. Your insurance may pay. If they do not you will have to pay.

Signing this does not mean you have given up any of your legal rights.

How will information about you be protected?
In the course of this research, we will collect information about you. This can be things that could be used to find out who you are (like your name, phone number, birthdate, address). We call this "identifiable private information". We will keep this information as confidential as possible. We will only allow study personnel to access your personal information. Your data will be stored on a password-protected

computer in a locked office. Any paper copies we receive from you will be stored in a locked file cabinet in a locked office in a building on the UNMC campus only accessible to study personnel.

In the future, we will take the identifiers off the information. It is possible that this information without identifiers could then be used for other research by us, or by another researcher, without asking you for your permission.

Who can see information about you?

We also will get medical information about you (like medical record number, medical history, or the results of physical exams, blood tests, x-rays, or other medical or research procedures). We call this "protected health information" or PHI. PHI is protected by a law called the HIPAA Privacy Rule. We will collect the smallest amount of PHI that we can. We will keep your PHI as confidential as possible.

By signing this consent form, you are letting us (the researchers listed on this consent form and other people involved in this research at the Organization) have access to your PHI. Your PHI will be used only for the purposes described in the section "What is the reason for doing this research study?"

You can change your mind and tell us to stop collecting your PHI for use in this research at any time by writing to the principal investigator. We can still use the PHI we have already collected. If you tell us to stop collecting your PHI, you will have to stop being in this research.

We may share your PHI with other groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- The HHS Office for Human Research Protections (OHRP)

There is currently no plan to end this study. You are letting us use and share your research data for as long as we want.

How will results of the research be made available to you during and after the study is finished?

In most cases, the results of the research can be made available to you when the study is completed, and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address:

Windy Alonso, PhD, RN, FHFSA
UNMC College of Nursing
985330 Nebraska Medical Center
Omaha, NE 68198-5330

What will happen if you decide not to be in this research study?
You can decide not to be in this research study. Deciding not to be in this research will not affect your medical care or your relationship with the investigator or the organization. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?
You can stop being in this research (withdraw) at any time. Just call the researcher or any research staff.

If you stop being in the research study it will not affect your care or your relationship with the investigator or the organization. You will not lose any benefits to which you are entitled.

You may be taken off the study if you do not follow instructions of the investigator or the research team.

You may also be taken off the study if we determine you are unsafe to exercise following your exercise test.

Any research data we have already collected can still be used in the research.

You can decide later that you do not want us to use your stored samples for other research. To stop the use, contact a member of the research staff listed at the end of this consent form.

Will you be given any important information during the study?
We will tell you right away if we get any new information that might make you change your mind about being in the study.

What should you do if you have any questions about the study?

We gave you a copy of *"What Do I Need to Know Before Being in a Research Study?"*

If you ever have any questions about this study, call the Principal Investigator or anyone else listed on this consent form.

What are your rights as a research participant?
You have rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning your rights, or want to discuss problems, concerns, obtain information or offer input, or make a complaint about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
    - Telephone: (402) 559-6463.
    - Email: IRBORA@unmc.edu
    - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
    - Telephone: (402) 559-6941
    - Email: unmcrsa@unmc.edu

Documentation of informed consent
You are deciding whether to be in this research study. Signing means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects You have had your questions answered.
- You have decided to be in the research study.
- You have been told you can talk to one of the researchers listed below on this consent form if you have any questions during the study.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject_____Date_____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate

Signature of Person Obtaining Consent_____Date_____

Authorized Study Personnel
Principal
* Alonso, Windy (Windy)
alt #: 402-559-8342
degree: PhD, RN

Secondary
* Pozehl, Bunny (Bunny)
phone: 402-559-3182
alt #: 402-429-5289
degree: PhD ANP-BC ACNP-BC FAHA

Participating Personnel
* Diederich, Theresa
phone: 402-559-7528
alt #: 402-559-5151
degree: APRN, MSN

* Lundgren, Scott
phone: 402-559-5151
alt #: 402-888-1147
degree: DO

Lead Coordinator
* Salahshurian, Erin
alt #: 402-559-6554
degree: RN, BSN