**NK3-11 Informed Consent**

**Penrose St. Francis Health Services**

**Colorado Springs, CO**

**Consent to be a Research Subject**

**Title**: Do Medically Supervised Exercise Programs Decrease Hospital Readmissions and Increase Quality of Life for Subjects Recently Hospitalized and Diagnosed with Congestive Heart Failure?

**Principal Investigator**: Debbie Avery, BSA, RN, 719-776-4761

**Funding Source**: None

## Introduction

You are being asked to be in a research study because you have been diagnosed with Congestive Heart Failure (CHF). This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study at any time. You can skip any questions that you do not wish to answer. The decision to withdraw will not affect your medical care.**

Before making your decision:

* Please carefully read this form or have it read to you.
* Please ask questions about anything that is not clear.

Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

## Study Overview

## A few medical studies have shown that people with a diagnosis of Congestive Heart Failure have improved their stamina and heart functioning by doing easy exercises. This study will gather information on the possible effect of personalized exercise instructions on your stamina and health status.

## Procedures

## If you decide to participate, you will be asked to take the “Minnesota Living with Heart Failure” questionnaire and have a senior fitness test conducted. An exercise physiologist trained to observe you medically will develop personalized exercises for you. Your blood pressure, pulse and oxygen concentration will be measured before, during and after your exercise. A registered nurse will help you to better understand your disease and how to take care of yourself. She can also help you better understand your hospital discharge instructions and help you follow them. You must agree to come to the Health Learning Center Gym for the exercise program two to three times per week for 12 weeks. We will enroll 30 people who can complete the entire program in this study.

## Risks and Discomforts The risks of this study are possible shortness of breath with exercise. If you need oxygen, it will be provided. Your oxygen will be monitored during your exercise. Your muscles may be sore from the exercise. An irregular heart beat may occur during exercise. For people with heart disease, participating in any activity that involves exertion, there is a slight risk of heart attack, lung congestion, chest pain requiring hospitalization, or a fall with injury.

## Benefits

The benefits of participating in this study are improved ability to do your everyday activities, a better understanding of your disease and how to take care of yourself. You might avoid being admitted to the hospital within 30 days due to your heart failure becoming worse.

##### Compensation

There is no monetary compensation for being in this study.

**Cost to you**

Please check with your insurance company to see if this program is covered by them. If your insurance does not cover the cost of the program it is $46 per month. There is assistance available through Penrose St. Francis Foundation if you cannot afford the fee.

###### Confidentiality

Your information will be kept in a locked office and on a password protected computer. Any information used in the review of this study will be de-identified (your identity will not be released).

## Voluntary Participation and Withdrawal from the Study

You have the right to leave a study at any time without penalty. You may refuse to do any procedures you do not feel comfortable with, or answer any questions that you do not wish to answer. If you do not come to the gym at least two times a week, you may not be in this study.

## Contact Information

Contact Debbie Avery, 719-776-4761

* if you have any questions about this study or your part in it,
* if you have questions, concerns or complaints about the research, or
* if you would like information about the survey results when they are prepared.

Contact the Institutional Review Board (IRB) Coordinator at 719-776-2514

* if you have questions about your rights as a research participant, or
* if you have questions, concerns or complaints about the research.

## Consent

A copy of this consent form will be provided to you.

I understand the above information and voluntarily consent to participate in the research.

Signature of Participant Date

Print Name:

Signature of Person Obtaining Consent Date