FIU IRB Approval:	05/22/2019
FIU IRB Expiration:	05/22/2022
FIU IRB Number:	IRB-19-0182

FIU | FLORIDA INTERNATIONAL UNIVERSITY

ADULT CONSENT TO PARTICIPATE IN A RESEARCH STUDY
HEART FAILURE PATIENTS' PERCEPTIONS OF PREPARATION FOR SELF-CARE

SUMMARY INFORMATION

You are being asked to be in this study because of your heart failure diagnosis. We would like to know your perceptions of preparing to take care of yourself after returning home.

Things you should know about this study:

- **Purpose:** The purpose of the study is to compare the health and healthcare charges of two groups. One group will receive routine hospital care. The other group will receive routine hospital care and follow-up phone calls by a nurse practitioner (NP).
- **Procedures**: If you choose to participate, you will be asked to complete 3 questionnaires at repeated times. Those in the second group will receive weekly nurse practitioner phone calls to check if you need assistance with any health care concerns. Those who receive weekly nurse practitioner calls, may also call the nurse practitioner by phone Monday through Friday 8:00 AM to 4:30 PM.
- **Duration:** This will take about 8 weeks to complete.
- **Risks**: The main risk or discomfort from this research is that answering some questions may cause you to feel uncomfortable. You are free to skip or not answer any question.
- **Benefits:** No direct benefit can be promised to you for taking part in this study. However, people may have health care information available to them quicker from nurse practitioner follow-up phone calls which is a benefit.
- **Alternatives:** There are no known alternatives available to you other than not taking part in this study.
- **Participation:** Taking part in this research project is voluntary.

Please carefully read the entire document before agreeing to participate.

PURPOSE OF THE STUDY

You are being asked to be in a research study. The principal investigator of this study is Valrie Reid, APRN, a PhD student in the College of Nursing and Health Sciences at FIU. You are being asked to be in this study because of your heart failure diagnosis. The purpose of this study is to compare the health and healthcare charges of two groups. One group will receive routine hospital care. The second group will receive routine hospital care and follow-up phone calls by a nurse practitioner (NP). The participants in the second group will be able to contact the nurse practitioner by phone Monday through Friday 8:00 AM to 4:30 PM. The phone calls will begin on the first week after you are discharged from the hospital.

NUMBER OF STUDY PARTICIPANTS
If you decide to be in this study, you will be one of 154 people in this research study.

DURATION OF THE STUDY
Your participation will involve 8 weeks of follow-up after hospital discharge.

PROCEDURES
If you agree to be in the study, we will ask you to do the following things:
You will be randomly assigned by chance, "like the flip of a coin" to one of 2 groups, the routine hospital care group or the nurse practitioner follow-up phone calls.

Routine Hospital Care Group:
If you are assigned to this group, you will receive the routine hospital discharge care according to the hospital's standards (normal care after you leave the hospital). After hospital discharge you will be interviewed by telephone every other week (7 times). The research assist will call you and ask you to answer some questions from 3 questionnaires and also ask if there were any emergency room visits, urgent care visits or hospitalizations after you were discharged from the hospital. The study team will also ask what their charges were for these visits. Each phone interview will take about 15- 20 minutes to complete.

Nurse Practitioner Follow-up Telephone Call Group:
If you are assigned to this group, you will receive the routine hospital discharge care according to the hospital standards and additional nurse practitioner follow-up phone calls. After hospital discharge, you will have a total of 8 weekly follow-up phone calls. The nurse phone calls will begin on the 7th day after hospital discharge, then on day 14, 21, 28, 35, 42, 49 and 56. Each phone call will take about 10 minutes for a total time of an hour and twenty minutes for all 8 nurse practitioner follow-up phone calls. When the nurse practitioner contacts you by phone, you will be asked about your health and if you need assistance with any health care concerns you may have. You will also be able to contact the nurse practitioner by phone Monday through Friday 8:00 AM to 4:30 PM. if you have any health concerns. In addition, starting on the 7th day after you are discharged from the hospital, then every other week (7 times) the nurse practitioner will ask you to answer some questions from 3 questionnaires and also ask if there were any emergency room visits, urgent care visits or hospitalizations after hospital discharge. The nurse practitioner will also ask what the charges were for these visits. Answering the questionnaires will take about 15- 20 minutes to complete.

RISKS AND/OR DISCOMFORTS

The study has the following possible risks to you: There is a small chance that you may feel uncomfortable answering some questions. You may skip or not answer any question.

BENEFITS

The study has the following possible benefits to you: There are no direct benefit promised to you for taking part in this study. However, people may have health care information available to them quicker from nurse practitioner follow-up phone calls which is a benefit. Your participation will provide an indirect benefit in helping to better understand how people with a diagnosis of heart failure perceive their preparation for taking care of themselves after hospital discharge.

ALTERNATIVES

There are no known alternatives available to you other than not taking part in this study. Any significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you.

CONFIDENTIALITY

The records of this study will be kept private and will be protected to the fullest extent provided by law. In any sort of report we might publish, we will not include any information that will make it possible to identify you. Research records will be stored securely, and only the researcher team at Florida International University will have access to the records. However, your records may be inspected by authorized University or other agents who will also keep the information confidential.

All of the information you give, including the study's questionnaires, and phone calls, will be kept confidential. There will be no names on any of the information we get from you. Each person who participates will be assigned a study identification number just for the study, so that we can keep all of your information together. The file that connects your name with the identification number and the information you provide will be stored in separate locked file cabinets in the study office at Florida International University. Information collected for this study will be filed and located separately from the Consent Form, due to possible connection of personal information.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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 website at anytime.

USE OF YOUR INFORMATION

Identifiers about you might be removed from the identifiable private information and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

COMPENSATION & COSTS

You will receive a payment of two $15 gift cards for your participation. There are no costs to you for participating in this study. Any costs you incur from the phone calls to or from the nurse practitioner will be your responsibility.

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MEDICAL TREATMENT

Routinely, FIU, its agents, or its employees do not compensate for or provide free care for human subjects in the event that any injury results from participation in a research project. If you become ill or injured as a direct result of participating in this study, contact your regular medical provider. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be billed. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not routinely available.

RIGHT TO DECLINE OR WITHDRAW

Your participation in this study is voluntary. You are free to participate in the study or withdraw your consent at any time during the study. You will not lose any benefits if you decide not to participate or if you quit the study early. The investigator reserves the right to remove you without your consent at such time that he/she feels it is in the best interest.

RESEARCHER CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues relating to this research study you may contact Valrie Reid at 305-788-9482, Florida International University or vreid004@fiu.edu

IRB CONTACT INFORMATION

If you would like to talk with someone about your rights of being a subject in this research study or about ethical issues with this research study, you may contact the FIU Office of Research Integrity by phone at 305-348-2494 or by email at ori@fiu.edu.

PARTICIPANT AGREEMENT

I have read the information in this consent form and agree to participate in this study. I have had a chance to ask any questions I have about this study, and they have been answered for me. I understand that I will be given a copy of this form for my records.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date