Subject Name: _____

Last 4 SSN_____ **Date:** _____

Title: Telehealth, Heart Failure, and Improving Quality of Life

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Principal Investigator: Jacqueline Gannuscio DNP, ACNP **VAMC: 688**

1. INTRODUCTION

This document is to ask you to participate in a study that is seeking to determine whether there is a difference in your quality of life, as a heart failure (HF) patient receiving care through the telehealth program or face to face visits with HF doctor. Your participation in the study is voluntary. This form will give you information about the research study, so you are well informed before you make a decision to take part in it. This form may contain words that you do not understand. Please do not hesitate to ask the Dr. Gannuscio or Ms. Callender any questions, if you are not clear about it.

2. PURPOSE OF THE STUDY

The purpose of the study is to determine whether there was a difference in the quality of life for veterans with heart failure (HF) receiving care through Telehealth compared to veterans receiving face –to-face (usual) care.

You are being asked to participate in this study because, you have been diagnosed with heart failure, and you receive you care at Washington DC Veterans Affairs Medical Center (DC VAMC). Your information will be used to help us better understand the care you receive in the Telehealth program or the primary care clinics. Also, the results of the study will be used to guide future research and to provide patients the highest quality of care in this area.

3. PROCEDURES

The study will be conducted at the Washington DC VAMC, Cardiology Department and Care Coordinator Home Telehealth (CCHT) Program. A total of 52 participants will be included in the study. It is projected to last approximately one year. The Principle Investigator for this study is Dr. Jacqueline Gannuscio, DNP, ACNP, a full-time member of the VAMC staff.

If you agree to participate in the study, you will be given the Minnesota Living with Heart Failure (MLHF) Questionnaire to complete during a regularly scheduled clinic visit, or you may be scheduled for a visit specifically to complete the questionnaire. The questionnaire is a self- assessment tool that will be used to assess your understanding and awareness of your physical, emotional, social and mental health on your quality of life. It is a 6-point scale that will be used to show how much your disease prevents you from living as you desire. It will take approximately 15-20 minutes to complete the survey. All heart failure patients are eligible to participate in the study. Your participation in the study will only last as long as it takes to complete the questionnaire survey.

4. RISKS

This research involves completing a questionnaire only. It may involve the risk of loss of privacy and confidentially, psychological stress or inconvenience. Every effort will be made to keep your information confidential. If you do not want to respond to some or the entire question, you can mark zero to indicate that it does not apply, or that you do not wish to answer.

5. BENEFITS

Participation in the study may not benefit you at this time. Your involvement in this study may provide information that will help other heart failure patients receiving care in the future.

6. PRIVACY & CONFIDENTIALITY

The Veterans Health Administration (VHA) of the Department of Veterans Affairs (VA) complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and it privacy regulation which, together with all other applicable laws protects your privacy. The ways we do this are describe in our " Notice of Privacy Practices." If you do not have a copy, the primary investigator or co-investigator will give it to you.

In order to do the research, Dr. Gannuscio and the co-investigator will keep the information about you in your medical record and other research restricted file. When you sign this form, you will authorize the Veterans Health Administration (VHA) to allow Dr. Gannuscio and co- investigator to use your medical data. This information includes your name, social security number, and date of birth, ethnicity, ejection fraction, New York Heart Association classification score, and unique identifying code. No identifiable data will leave the Washington DC VAMC.

If you do not sign this authorization, you cannot participate in the study. The authorization to use your information will last indefinitely. You may revoke this authorization at any time. To do this, you should write to Dr. Gannuscio, or ask a member of the study team to give you a form to revoke the authorization.

If you revoke the authorization, you may not continue to be in the study. Dr. Gannuscio and the research team may continue to use any information that has already been collected and combined with information from other participants. However, no new information will be collected. If you refuse the

authorization or revoke the authorization, you will continue to receive all of the medical care and benefits for which you are eligible.

Federal and local regulations may require review of your medical and research records by representatives of the Food and Drug Administration (FDA), Government Accountability Office (GAO), the Veterans Affairs (VA), and the Institutional Review Board (IRB) of the medical center.

Your research data and records will not be available for your review until after the completion of the study. Despite all of our efforts and precautions, there is always a possibility that some of your information may be used or disclosed by the authorized recipient in a way that the law will no longer protect it. Please ask Dr. Gannuscio if you have any questions or concerns.

We will let you and your physician know of any important discoveries made during this study, which may affect you, your condition or your willingness to participate in this study. If the results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your explicit consent.

We will maintain your privacy and the confidentiality of the research record. No information by which you may be identified will be released or published without your authorization unless required by law. Dr. Gannuscio will have possession of all data including questionnaires. Other research staff members will have access to them, however; they will be stored in a secure location in accordance with the record control schedule. At that time, they will be destroyed.

7. SPECIAL INFORMATION

You are not required to take part in this study. Your participation is entirely voluntary. You may refuse to participate now, or you may withdraw from the study at any time after giving your consent. It will not interfere with you regular medical treatment if you are a patient.

There will be no costs to you for any treatment or testing done as part of this study if you participate in this study. Eligibility for necessary medical care is based on the usual VA eligibility policy, and it is not guaranteed by the participation in the study. The VAMC will provide appropriate medical treatment if you are injured as a result of your involvement in this study. Unless you were injured because, you did not follow study procedures.

Additional compensation may or may not be payable in the event of physical injury arising from the study under applicable federal law. Further information about compensation may be from the medical administration service at this VA medical center.

If you have questions about your rights, you may contact the Associate Chief of Staff for Research and Development, Dr. M. Blackman, at 202-745-8133,or the Chairman of the Human Studies Committee, Dr. C. Gibert at 202-745-7560.

A copy of this consent form will be placed in your medical record.

8. AFFIRMATION FROM SUBJECT

Participant Affirmation

I have read or have had read to me all of the above. Dr. Gannuscio DNP, ACNP or Ms. Callender, RN, MSN, DNP Student has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatments available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my records will not be revealed unless required by law.

In case there are medical problems or questions, I have been told I may call Ms. Gannuscio at 202-745-8000 extensions 57297 during the day and 202-745-8247 for emergencies.

I understand the explanation of my rights as a research subject, and I voluntarily consent to participate in this study. I understand the explanation of what the study if about and why it is being done. I will receive a signed copy of this consent form.

_____ _____

Participant's Signature Date

I have informed the participant of the intent, nature benefits and risks of the research project. I judge that he/she understood my explanation and that his consent was given freely.

_____ _____ _____

Consent Informant Signature Print Name Date