# Informed Consent Form

An evaluation of telenursing with or without remote monitoring to determine impact of Hospitalization Rate when compared to usual care for patients diagnosed with idiopathic pulmonary fibrosis

Dated: 8/31/2020

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**Institutional Review Board**
**Informed Consent Document for Research**

**Principal Investigator: Lisa Lancaster, M.D.** **Revision Date: December 10, 2018**
**Study Title: An evaluation of telenursing with or without remote monitoring to determine impact of Hospitalization Rate when compared to usual care for patients diagnosed with idiopathic pulmonary fibrosis.**
**Institution: Vanderbilt University Medical Center**

This informed consent applies to Adults.

Name of participant: _____ Age: _____

**The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.**

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

## 1. What is the purpose of this study?

You are being asked to take part in this research study because you have been diagnosed with Idiopathic Pulmonary Fibrosis (IPF).

The purpose of the study is to determine if telenursing with or without remote monitoring will reduce rate of hospitalizations when compared to usual care. Telenursing is a new concept to healthcare where a nurse will contact you on a regular planned basis to provide information about your disease and treatment as well as ask questions related to illness. Remote monitoring is another new concept and requires you to complete objective measurements of your health at home and report these to your healthcare team on a regular basis. This study will also evaluate if telenursing with or without remote monitoring reduces respiratory complications and improves compliance in specific areas of healthcare, quality of life scores, depression scores, and ultimately mortality.

We expect about 150 patients will participate in this study. This study is being done at Vanderbilt Medical Center.

## 2. What will happen and how long will you be in the study?

Before you may participate in this study, you will be asked to read and sign this consent form.

Because we are determining if our intervention (telenursing with or without remote monitoring) will impact multiple aspects related to the diagnosis and outcomes associated with idiopathic pulmonary fibrosis (IPF), we need to compare these to usual care. To do this, participants will be randomly assigned into one of three groups. The group you are assigned to is by chance, like the roll of a die. This is known as randomization. Participants in Arm 1 will continue to receive usual care. Participants assigned to Arm 2 will receive usual care with telenursing. Participants assigned to Arm 3 will receive usual care with telenursing and remote monitoring. There is a one-third chance, or 33% chance, that you will be assigned to one of these arms.

If you agree to participate, you will be asked to remain in the study for at least one year, or until you receive a lung transplant, or until the investigator ends the study. You have the right to stop taking part in the study, or any portions of the study, at any time.

After you have read and signed this Informed Consent Form, you will randomized to one of the three groups. You will be told which group to which you are randomly assigned.

**Usual Care (Arm 1)**

If you are assigned to the Usual Care arm (Arm 1), you will continue to receive the standard of care you would normally receive at our center. You will receive teaching materials about your lung disease and treatment options as well as our plans for managing your illness. You will be counseled about your lung disease by your physician as well as our nurses in our center. You will receive phone calls when needed from your IPF nurse practitioner or nurse case manager.

The results of the tests and procedures that you complete for the management of your disease will be collected in our de-identified database. We will capture the results of tests that are completed at our center as well as the results of tests that are completed by your regular doctors.

In addition to the above, we will ask that you complete several questionnaires. The answers to the questionnaires help us understand your feelings about your quality of life, knowledge of your disease, compliance with therapies, hospitalization and illnesses, and depression. We will give you these questionnaires when you sign this consent and at about every six months. These questionnaires may be sent to you electronically via an email to complete on-line through our web-based survey, or given to you in paper format, whichever you prefer.

**Usual Care with Telenursing (Arm 2)**

If you are assigned to the Usual Care with Telenursing arm (Arm 2), you will continue to receive the standard of care you would normally receive as described above, however, in addition, you will receive a notebook outlining the Telenursing intervention.

Your notebook will contain a calendar and schedule related to phone calls that will be made between your and the IPF Nurse Practitioner or Case Manager. There will be two phases of phone calls: Education Phase and Management Phase. In the Education Phase, we will schedule one phone call every week for 7 or 8 weeks to formally discuss your lung disease as well as various topics that are important to patients with IPF, such as oxygen, pulmonary rehabilitation, and lung transplant. During the Management Phase, our scheduled phone calls will occur within a week after your clinic-based visit to ensure all your questions have been answered, referrals have been made, and prescriptions have been obtained. We will also schedule a phone call at a time point between your out-patient office visits to determine your health status and ask questions related to possible illness and any changes in symptoms, such as shortness of breath.

The phone calls that will be made will occur via one of two ways, depending on the technology in your home. You will either receive a phone call at scheduled appointments, or an email inviting you to a ZOOM portal. You are welcome to share your ZOOM email to other caregivers or family members. The ZOOM platform will allow us to communicate in a video-conference nature allowing you to see your nurse case manager or practitioner as well as see the educational material that will be provided.

**Usual Care with Telenursing and Remote Monitoring (Arm 3)**

If you are assigned to the Usual Care with Telenursing and Remote Monitoring arm (Arm 3), you will continue to receive the standard of care you would normally receive as described in the Usual Care paragraph, as well as the Telenursing intervention described above. In addition, you will be given two devices: a home hand-held spirometer and a pulse oximeter.

This study is utilizing the Spirobank Smart spirometer. You will be asked to use the hand-held spirometer daily at about the same time every day. You will receive instruction from the study nurse as well as printed materials and a website that provides visual instruction on how to use the device. You will be asked to track your progress by either logging your spirometric values in an app called 'patientMpower' that will need to be downloaded to your smartphone or tablet. You will be asked to monitor your spirometric values and will be provided instruction on when to contact your telehealth

nurse. You will be asked to return the device at the end of the study. If you do not have a smartphone or tablet, or do not want to download the app, you will not be able to participate in this portion of the study.

This study is using the Nonin pulse oximeter. You will be asked to use the pulse oximeter daily at about the same time every day. You will receive instruction from the study nurse as well as printed materials. You will be asked to track your progress by either logging your oxygen saturation and heartrate in the app mentioned in the previous paragraph that will need to be downloaded to your smartphone or tablet. You will be asked to monitor your oxygen saturation values and will be provided instruction on when to contact your telehealth nurse. You will be asked to return the device at the end of the study. If you do not have a smartphone or tablet, or do not want to download the app, then you may track your results on the diary provided.

You will be asked to track your daily weight. You will be asked to step on a scale at your home and record your body weight at about the same time every morning.

You will be asked to transfer your daily spirometric, pulse oximetry, heartrate, and weight measurements to your telehealth nurse through a secure portal, the app, or via the mail (or email) at least monthly. You will be given instructions on how to do this.

**3. Costs to you if you take part in this study:**

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research.

However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

**4. Side effects and risks that you can expect if you take part in this study:**

There are risks to being in any research study.

Questionnaires – Completing questionnaires related to quality of life and depression may make your feel uncomfortable. Sometimes answering several questions is mentally tiring. It is important that you complete the questionnaires, however, you do not have to answer questions that make you feel uncomfortable. You can complete the questionnaires at your own pace.

Daily measurements of lung function and oximetry – Measuring and recording your spirometric values, pulse oximetry and heartrate every day may become tiring, monotonous, or cumbersome. Recording your spirometry especially as the numbers worsen (disease progression) despite taking your medication and following the advice of your healthcare providers can be depressing. You can stop the collection of these data points at any time.

Loss of confidentiality - There is a small risk of a breach of confidentiality. Measures are in place to prevent this from happening. Further explanations of these measures are located in Section 13.

**5. Payment in case you are injured because of this research study:**

If it is determined by Vanderbilt and the Investigator, that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

**6. Good effects that might result from this study:**

a) The benefits to science and humankind that might result from this study:
By taking part in this study you will help us understand other ways of effectively manage this lung disease.
b) The benefits you might get from being in this study:
There is no guarantee that you will receive any benefit by taking part in this study.

**7. Other treatments you could get if you decide not to be in this study:**

You do not have to participate in this study to receive healthcare for your IPF. You may continue receiving standard of care and not participate.

**8. Payments for your time spent taking part in this study or expenses:**

You will not be paid to be a part of this study.

**9. Reasons why the study doctor may take you out of this study:**

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

The study team may decide to take you off this study at any time if it is in your best interest, if you do not complete the telenursing phone calls, if you do not make any attempt to complete the daily spirometric or pulse oximetry procedure, or if the study is stopped.

**10. What will happen if you decide to stop being in this study?**

You can decide to stop being in the study at any time. If you decide to stop being in the study, please notify the study team. The standard of care for your lung disease by your lung doctor will not change.

**11. Who to call for any questions or in case you are injured:**

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Lisa Lancaster, at 615-936-2298. The emergency contact number (for after usual business hours) is 615-936-0393.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

**12. Clinical Trials Registry.**

A description of this clinical trial will be available on 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.

**13. Confidentiality:**

This research study may be performed only by collecting and using your medical information. Your study records will be kept as confidential as possible. Only a number and initials will be used to identify you. You will not be personally identified in any reports or publications that may result from this research study.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt Dr. Lisa Lancaster, and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

**14. Authorization to Use/Disclose Protected Health Information**

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has, been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Vanderbilt University Medical Center may share the results of your study and/or non-study linked medical records, laboratory tests, reports, questionnaire forms and results, as well as other parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the VUMC Institutional Review Board, Vanderbilt University. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Lisa Lancaster, in writing and let her know that you withdraw your consent. Her mailing address is [redacted]5. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

**If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.**

**STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY**

**I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.**

| | |
|---|---|
| Date | Signature of patient/volunteer |

Consent obtained by:

| | |
|---|---|
| Date | Signature |
| | Printed Name and Title |

Time