UNIVERSITY OF WASHINGTON
INFORMED CONSENT FORM
FOR CYSTIC FIBROSIS PARTICIPANT

Sponsor / Study Title:	**National Institutes of Health (NIH) / Preparation for lung transplant discussions and decisions among people with cystic fibrosis [LTx READY CF 2]**
Principal Investigator: (Study Doctor)	**Kathleen Ramos-Alexander, MD**
Telephone:	**(503) 583-2869** **(206) 543-0393 (24 Hour)**
Address:	**University of Washington Medical Center, Montlake Campus** **1959 NE Pacific Street** **Seattle, WA 98195-6522**

You are invited to take part in a research study. Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form.

KEY INFORMATION
This research study aims to understand how to best prepare people with cystic fibrosis (CF) for discussions and/or decisions about lung transplant. Lung transplant is a possible treatment option for advanced CF.

Involvement in this study will last 6 months. There will be a total of four sessions that will take place remotely, using Zoom videoconferencing, and one CF clinic visit. The study team and the University of Washington are receiving financial support from the National Institutes of Health (NIH) who provided funding for this research.

During this study, you will have access to an educational website that contains information about lung transplant. You will be asked to respond to surveys and will also be asked to have a CF clinic visit audio recorded. No recording will occur without expressed permission from you, your provider, and anyone else present during the visit. Researchers at the University of Washington may contact you for additional research opportunities related to this study.

The study staff acknowledges that lung transplant can be a sensitive subject for many people. Participants will be able to control the type of information they read in the research website. Your mental health will be a priority and closely monitored throughout this study.

BACKGROUND AND PURPOSE
You are being asked to participate in this research study because you have CF and low lung function (an FEV_1 less than or equal to 50% of the predicted normal value).

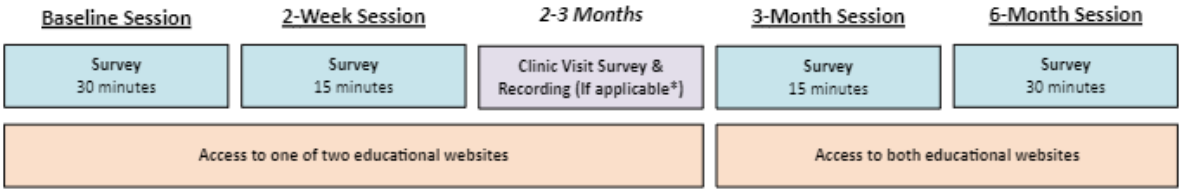
Lung transplant is an option for treating end-stage lung disease in people living with CF. In the United States, more CF patients with advanced lung disease (very low lung function or FEV_1) die each year than undergo lung transplant. Additionally, more than half of people with CF who die without lung transplant are never referred for consideration. The CF Foundation (CFF) established guidelines that recommend individuals with CF have conversations about lung transplant with their CF doctor every year once their FEV_1 is less than 50% of predicted. Considering lung transplant as a treatment option ahead of when it is medically needed allows more time to learn about lung transplant and address any barriers to lung transplant that may exist.

The purpose of this research study is to see if people with CF may benefit from using lung transplant educational resources as they prepare for lung transplant discussions and/or decisions. Transplant discussions may occur with CF providers and/or loved ones. Researchers will introduce an educational website that contains information about lung transplant and assess whether it improves preparedness for shared decision making about lung transplant.

Approximately 150 individuals with CF will participate in this study.

WHAT WILL HAPPEN DURING THE STUDY?

Your participation in this study will last six months and will include a total of four study sessions that take place remotely using Zoom videoconferencing and one CF clinic visit. Study procedures are as follows:



**No recordings will occur without expressed permission from you, your provider, and anyone else present during a clinic visit.*

Survey – You will be asked to complete a survey at each session. Surveys will assess your preparedness for decision making about lung transplant, knowledge about lung transplant, mental health, evaluation of the research website(s), etc. A survey after your CF clinic visit will assess your discussion with your doctor and evaluate whether you experienced any discrimination or bias during the visit. Surveys will take approximately 15-30 minutes to complete and you may refuse to answer any questions you do not feel comfortable answering.

Research Website – During the Baseline Session, you will gain access to a research website and will be given a login for continued use for the remainder of the study. For three months, you will be randomly assigned by chance (like the flip of a coin) and will have access to one of two websites that contains educational information about lung transplant. You will have a 50% (1 in 2) chance of receiving one website and a 50% (1 in 2) chance of receiving the other website. After three months, and completion of a regularly-scheduled CF clinic visit, you will gain access to the other website. Your use of the research website will be captured using website analytics (for example, time spent using the tool, number of page views, number of clicks, and which areas of the website were visited). The research website captures information about when (time of day) and where (which city) you use the website.

Medical Record Access - During this study, we will access your medical records from the local electronic health record. The information we access and obtain will be clinically relevant to this study. This information could include your past medical history, demographic information, medications, hospitalizations, information about lung transplant referral, etc.

Clinic Visit and Audio Recording – A routine CF clinic visit will be scheduled between 2 and 3 months after you start the study. The clinic visit can be in person or telemedicine. You and your doctor will be asked to fill out a survey after the clinic visit. You may be asked to have the visit audio recorded and transcribed. This will allow researchers to better understand the discussion between you and your doctor and assess whether you discussed lung transplant. No recording will occur without expressed permission from you, your provider, and anyone else present during the clinic visit.

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS
You may be exposed to low risk by participating in this study.

Audio recordings will be stored indefinitely in a password protected file on a University of Washington server. You will not be given the opportunity to listen to these recordings, but you may request access to the transcribed version of the interview to confirm accuracy. All recordings will be transcribed and de-identified. These de-identified transcripts may potentially be shared with other researchers.

You will have audio recording of your voice so there is the risk that someone may recognize your voice. However, once the audio recordings are collected, each audio file will be coded. The recordings will be transcribed by the study staff and no names will appear in the written transcripts.

Risks of study procedures:
Common (greater than or equal to 1/100 to less than 1/10)

- Psychological risk: Discussing and considering lung transplant as a treatment option for CF can be a sensitive topic. It is possible that you may experience distress from thinking about or reading about lung transplant on the research website. If you have questions about your clinical care, you should talk to your CF doctor or mental health provider for medical advice. Additionally, over the course of your involvement in this research study we will monitor your mental health by administering mental health assessments, including the PHQ-9 (depression) and GAD-7 (anxiety) surveys. It is possible that you may experience psychological discomfort by completing these assessments. To protect your wellbeing, if abnormal results are reported on the PHQ-9 or the GAD-7 surveys, study staff will notify your CF doctor for follow-up care. Additionally, if there are safety concerns based on your response to a PHQ-9, our study physician may call you directly to discuss a safety plan.

Very rare (less than 1/10,000)]

- Risks to confidentiality: As with any research study, there is a potential risk of loss of confidentiality. We will take all precautions to ensure the confidentiality of your data if identifiable information is obtained. Your name will not be used in any publications about this study or the research website.

There also may be risks that are unknown at this time.

ALTERNATIVES TO PARTICIPATION
This research study is for research purposes only. The only alternative is to not participate in this study. Choosing not to participate in this study will not affect your future care.

BENEFITS
You may benefit as a result of your participation in this study as the research websites may increase your preparedness for shared decision making and decrease discomfort related to lung transplant discussions. There is, however, no guarantee that you will benefit from your

participation in this study. Information learned from the study may help other people with CF in the future.

NEW FINDINGS
Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

COMPENSATION FOR PARTICIPATION
You will be paid at the rate of $30/hour up to a total of $200 if you complete all study procedures. You will be paid for the sessions you complete according to the following schedule:

- Baseline Session (30 min.): $15
- 2-Week Session (15 min. + 2 hr. website use regardless of actual usage): $70
- Clinic Visit Audio Recording (60 min.): $30 – *if applicable*
- Post-Clinic Visit Survey (15 min.): $10
- 3-Month Session (15 min.): $10
- 6-Month Session (30 min.): $15
- Completion Bonus: $50 for completion of the 4 study sessions and one CF clinic visit

If you do not complete the study, for any reason, you will only be paid for each study session you do complete. Compensation will be distributed in the form of a Tango gift card within 1-3 business days following each completed session. If you have any questions regarding your compensation for participation, please contact the study staff.

A device (for example, a tablet) and/or reliable internet connection (mobile Wi-Fi hotspot and pre-paid data) can be requested to make your participation in this study possible. They may be used for the duration of this study, but must be returned to the study staff once study involvement is completed.

CONFIDENTIALITY
Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The study doctor or persons working on behalf of the study, and under certain circumstances, the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

We have a Certificate of Confidentiality from the U.S. federal National Institutes of Health. This helps us protect your privacy for data that is stored in the United States. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information. You or a member of your family can share information about yourself or your part in this research if you wish.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person.

There are some limits to this protection. We will voluntarily provide the information to:

- A member of the federal government who needs it in order to audit or evaluate the research;
- Individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly

A description of this clinical trial will be available on http://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.

COSTS

There will be no charge to you for your participation in this study. The remote study sessions will be provided at no charge to you or your insurance provider. The routine CF clinic visit is a standard part of clinical care and will be billed to your insurance provider as usual.

FUTURE RESEARCH STUDIES

Identifiers will be removed from your personal health information collected during this study and may then be used for future research studies and/or distributed to another investigator for future research studies without additional informed consent. Additionally, the University of Washington study staff may use your identifiable information to contact you or your caregivers (friends and/or family) for additional relevant studies related to CF and/or lung transplant.

CLINICALLY RELEVANT RESULTS

During your involvement in this study, we will monitor your mental health through the use of various survey assessments, including the PHQ-9. In the event of an abnormal result (for example, reporting suicidal ideation or worsening depression) that requires clinical intervention, you will be contacted by a study doctor within 8 hours, and your survey results will be communicated to your CF doctor for follow-up care.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you have questions, concerns or complaints about the study such as:

- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation

Please contact the study doctor at the telephone number listed on the first page of this consent document.

An Institutional Review Board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00068003.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care.

The study doctor can stop your participation at any time without your consent for the following reasons:

- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

CONSENT

I have read (or had read to me) and have been informed about the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document.

A copy of the consent form will be emailed to you at an email address that you provide. Most computers already have PDF viewer software installed, which will allow you to open, read, or print the consent form. The email we send you will include a link to PDF viewer software (such as Adobe Acrobat Reader) in case your computer doesn't already have it. If you would prefer to receive a paper copy of the consent form at no cost to you, please reach out to your study contact.

If you wish to withdraw from the study, please reach out to your study contact or the study doctor using the information listed on the first page.

_____

Participant's Printed Name

_____ _____

Participant's Signature Date