INFORMED CONSENT FORM AND
AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR MEDICAL RECORD
INFORMATION FOR ADULTS / PARENT / LEGAL GUARDIANS
AND ASSENT FOR SUBJECTS 12 TO AGE OF MAJORITY

Sponsor-Investigators / Study Title:	**Patrick Flume, MD (Medical University of South Carolina), Christopher H. Goss, MD MSc (University of Washington) / "Standardizing Treatments for Pulmonary Exacerbations: A platform for evaluating treatment decisions to improve outcomes (STOP360)"**
Protocol Number:	**STOP360-IP-22**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

Potential Adult Subjects: This is a consent form. It provides a summary of the information the research team will discuss with you. If you decide that you would like to take part in this research study, you would sign and date this form to confirm your decision. If you sign and date this form, you will receive a signed and dated copy of this form for your records.

Potential Teen Subjects: This form also serves as an assent form. That means that if you choose to take part in this research study, you would sign and date this form to confirm your choice. Your parent or guardian would also need to give their permission and sign and date this form for you to join the study.

Parents/Guardians: You have the option of having your child or teen join a research study. This is a parental permission form. It provides a summary of the information the study team will discuss with you. If you decide that your child can take part in this study, you would sign and date this form to confirm your decision. If you sign and date this form, you will receive a signed and dated copy for your records. If you are the parent or legal guardian of a child who may take part in this study, your permission and the permission of your child will be needed. When "you" appears in this form, it refers to your child except where it says otherwise.

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of standard medical care is to help each patient.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of any research study is to answer questions. The purpose of this study is to look at pulmonary exacerbations in people with cystic fibrosis (CF) that need to be treated with antibiotics given through a tube inserted into a vein (intravenous or IV). A pulmonary exacerbation is a worsening of respiratory symptoms in people with CF that needs medical intervention. Both doctors and CF patients are trying to understand the best way to treat pulmonary exacerbations. This study is trying to answer the following questions about treating a pulmonary exacerbation:

- Do participants have the same improvement in lung function and symptoms if they are treated with one type of antibiotic (called beta-lactams or β-lactams) versus taking two different types of antibiotics (tobramycin and β-lactams)?
- Is taking one type of antibiotic just as good as taking two types?

WHY DO I HAVE THE OPTION TO JOIN THE STUDY?

You have the option to join this research study because you have cystic fibrosis (CF) and Pseudomonas aeruginosa (*Pa)*, and you are having a pulmonary exacerbation, which your doctor wants to treat with IV antibiotics.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 730 people with CF who are ages 6 years and older will take part in this study at approximately 60 hospitals and clinics around the United States and Canada.

IF I AGREE TO JOIN THE STUDY, WHAT WOULD I NEED TO DO?

If you agree to take part in the study, you will come to the study site for a total of 2 study visits over approximately the next 4 weeks. Additionally, you will participate in a follow up phone call approximately two weeks after your last study visit. Regardless of whether you decide to be in the study or not, your doctor will decide what antibiotics to use to treat your pulmonary exacerbation.

If you join the study, you will have some tests and exams which are described below.

If you meet the requirements to be in the study, during the first visit, you will be *assigned to one of two* interventions:

- Take IV tobramycin and β-lactams for 14 days (± 2 days)
- Take IV β-lactams only for 14 days (± 2 days)

Which intervention you are assigned to is done by chance. It is similar to flipping a coin. You and your doctor will know which group you are in.

Explanation of Study Procedures:

The tests that would be done if you join the study include:

- **Informed Consent:** We will explain the study to you. If you decide to participate you will be asked to review, sign, and date the consent and HIPAA authorization forms.
- **Medical History:** Your medical chart will be reviewed and you will be asked questions about your health including current and past illnesses and use of medications.
- **Demographic Information:** We will collect information about you such as sex at birth, birthdate and race.
- **Physical Exam**: Your doctor will examine your body for any abnormal signs and symptoms.
- **Weight and Height**: Your weight and height will be measured for this study.
- **Paper Questionnaires:** You will be asked questions about your health, quality of life, if you have ringing in your ears (known as tinnitus), and if you are having any problems with your balance (feeling dizzy or unsteady).
- **Electronic Questionnaires:** You will be asked to complete questions about your health and quality of life outside of clinic visits using your own cell phone or tablet device. To do this, you would need to download an application to your device. The application may not be able to be downloaded on some types of devices. If you are able to download the application, you would then register yourself by entering personal information such as your name, email address and mobile phone number. You will be asked to agree to the application Terms of Use. If you decide you do not want to agree, then you can choose not to use the application and still participate in the study. While the Terms of Use of the application may include statements limiting your rights if you are harmed in this study, you do not release the investigator, sponsor, institution, or agents from responsibility for mistakes, and these statements do not apply to the use of the application in this research

study. You will be notified to complete the questionnaires even if your visit is delayed or canceled; please complete the questionnaires when you receive them on your personal device.

- **Spirometry:** This test measures how much air your lungs can hold and how fast you can breathe out. You will take a deep breath and then blow into a mouthpiece as hard as you can and for as long as you can. You might have to wear soft nose clips during the test to stop air from escaping through your nose. You may take a medicine (bronchodilator) such as albuterol before doing spirometry.
- **Urine:** You will be asked to pee in a cup so we can collect and bank the samples for future researchers.
- **Urine:** At in person visits you will be asked to pee in a cup so we can collect and bank the samples for future researchers. We will also ask you to do a urine collection at home near the end of your antibiotic course (about Day 14). We will provide shipping materials and instructions for you to ship the specimen to the laboratory for research testing. We will contact you to remind you when it is time to do the collection.
- **Expectorated Sputum:** Sputum is mucus from your lungs. If you are able to produce sputum, we will ask you to breathe in deeply and cough hard several times to bring up sputum from deep in your chest. The sample will be collected for specimen banking.
- **Expectorated Sputum:** Sputum is mucus from your lungs. If you are able to produce sputum, we will ask you to breathe in deeply and cough hard several times to bring up sputum from deep in your chest. We will also ask you to do a sputum collection at home near the end of your antibiotic course (about Day 14). We will provide shipping materials and instructions for you to ship the specimen to the laboratory for research testing. We will contact you to remind you when it is time to do the collection.
- **Saliva:** You will be asked to collect saliva for this study. The sample will be collected for research testing.
- **Current Medications:** You will be asked about all medications and non-drug therapies you are currently taking.
- **Pregnancy Test:** All people who can potentially become pregnant will have a pregnancy test at the first study visit (1/2 tsp of either blood or urine). The test must be negative at the beginning of the study or you cannot join the study.
- **Routine blood tests**: If routine blood tests are done as part of your clinical care, we will collect the results from those tests.

Explanation of Study Visits:

Study Procedures	**Visit 1**	**Day 7 and Day 14 Electronic questionnaires only – no visit**	**Visit 2**	**Visit 3 (Phone Call)**
Informed Consent/HIPAA Authorization	X			
Demographic Information	X			
Medications Review	X			X
Questionnaires (paper)	X		X	
Questionnaires (electronic)		X		X
Height	X			
Weight	X		X	
Physical Exam	X		X	
Spirometry	X		X	
Urine Collection	X		X	
Expectorated Sputum	X		X	
Pregnancy Test	X			
Approximate length of visit	**3 hours**	**5 mins**	**2 hours**	**1 hour**

Study Procedures	**Visit 1**	**Day 7 – Electronic questionnaires only – no visit**	**Day 14 – Home specimen collection & electronic questionnaires only – no visit**	**Visit 2**	**Visit 3 (Phone Call)**
Informed Consent/HIPAA Authorization	X				
Demographic Information	X				
Medications Review	X				X
Questionnaires (paper)	X			X	
Questionnaires (electronic)		X	X		X
Height	X				
Weight	X			X	
Physical Exam	X			X	
Spirometry	X			X	
Urine Collection	X		X	X	
Expectorated Sputum	X		X	X	

Saliva	X			X	
Pregnancy Test	X				
Approximate length of visit	**3 hours**	**5 mins**	**30 mins**	**2 hours**	**1 hour**

Medication Restrictions

Please inform your study doctor of any medications and non-drug therapies that you are currently taking. Your study doctor will tell you whether you can continue using a particular medication or non-drug therapy while you are participating in this study. You will be asked not to take the following medications between Visit 1 and Visit 2:

- Investigational therapies
- Inhaled antibiotics that work against pseudomonas such as colistin, aztreonam (Cayston®) or tobramycin. Other names of inhaled tobramycin are TOBI, TOBI Podhaler, and Bethkis.
- Oral antibiotics or intravenous antibiotics that work against pseudomonas, such as ciprofloxacin or levofloxacin (other than the intervention you are assigned by this study)

HOW WILL THIS STUDY BE USED FOR FUTURE RESEARCH?

Study Data

The study data collected throughout the study is property of the sponsors and the Cystic Fibrosis Foundation (CFF). The data collected for this study will be retained in a secure manner. The data may be shared with other researchers and used in future research either alone or with your banked samples, but whether this will happen is not known at this time. The goal of future studies would be to help us understand CF better. Understanding more about CF helps us design CF research studies and take better care of people who have CF.

CF Foundation Patient Registry Data

You are also participating in the CFF's Patient Registry, a database that contains information about the clinical care of people who have CF (such as information about hospitalizations and medications). You were given a unique identification (ID) number to label your clinical care information when you joined this registry. As a part of the STOP360-IP-22 Study, we will collect your CFF Registry ID Number. Because we are collecting your CFF Registry ID Number in this study, it will be possible to link all of your clinical care information in the registry (past, present and future) to your banked samples and data from this research study.

Your CFF Registry ID may also be used to link data from STOP360-IP-22 with other studies that are linked with the CF Registry ID for future research studies.

What if I change my mind about sharing my CFF Registry information?

If you change your mind and no longer want to share your information from the CFF Registry, please tell the study doctor. If you change your mind after the study is over, you may contact the CFF at biorepository@cff.org.Your CFF Registry ID would no longer be used to link your

future registry information to the STOP360-IP-22 Study. However, any registry information that has already been linked to STOP360-IP-22 study data or specimens and given to researchers would continue to be used and cannot be removed.

Specimen Banking

Storing specimens so that they can be shared with other researchers in the future is called specimen "banking". In this study, you are being asked to bank your specimens (urine and sputum) for future research use.

The Cystic Fibrosis Foundation (CFF) has created a specimen bank to store specimens from CF research studies. The specimens in the bank would be used to learn more about CF.

- We will label your specimens with a barcode, not with your name or any other information that can directly identify you. Future researchers looking at the specimens will not be able to know who you are.
- We will store your samples at a specimen storage company contracted by the CFF.
- We will keep your samples indefinitely or until they are used up.
- The CFF and the CFF Therapeutics Development Network Coordinating Center (TDNCC) keep a list linking the barcodes on your samples to your identifying information. It is kept in a separate secure database that is protected with passwords.
- Future research may require some of your health information. If this happens, only the requested information would be pulled from your study data or registry data and the information will be coded so that the researchers will not be able to identify you.
- We will only share your specimens and data with researchers who have approval from their Institutional Review Board (IRB) and the Cystic Fibrosis Foundation (CFF). For-profit companies may also ask to use the samples and will need the same approval before any samples and/or data will be given to them.
- Results from research studies using the specimen bank may be published in medical journals or presented at scientific meetings, but your name will not be used.
    - We will not be able to give you the results from the research that is done using your specimens.
- If any new therapies, products or procedures are developed from studying your samples, you would not receive any money.

What if I change my mind about Specimen Banking?

If you change your mind and no longer want to bank your samples, please tell the study doctor. If you change your mind after the study is over, you may contact the CFF at biorepository@cff.org. All of your samples from this study that are still in the specimen bank would be removed, but any samples that have already been given to researchers would continue to be used and cannot be taken back.

WHAT ARE THE RISKS OR DISCOMFORTS THAT CAN HAPPEN FROM THIS RESEARCH?

There are potential harms or risks if you take part in this study. These risks are described in the table below.

Types of Antibiotic Medications:

The two types of antibiotics that will be studied will be prescribed clinically by your doctor and are approved for the treatment of pulmonary infections. It is likely that you have been treated with these types of antibiotics before for a pulmonary exacerbation. There are known risks related to these types of antibiotics.

Type of Antibiotic	**Possible Risk Associated with this Type of Antibiotic:**
Beta-lactams	The most commonly reported side effects include abdominal pain, diarrhea, nausea and vomiting, skin rash, decreased white blood cells, decreased platelets, and decreased appetite. Less common but serious side effects can include an allergic reaction with swelling of the tongue and throat or difficulty breathing.
Aminoglycosides (Tobramycin is a type of aminoglycoside)	The risks include kidney injury, permanent hearing loss, ringing in the ears, permanent balance problems, and rarely muscle weakness and allergic response (including a severe allergic reaction called anaphylaxis).

Study Procedures:

There are some minimal risks related to the procedures used in the study. Some of these procedures you may have had at your standard clinic visits. In addition, these procedures may involve risks that are unexpected.

Procedure	**Possible Risk Associated with Procedure**
Expectorated Sputum	Coughing up sputum may cause brief coughing and shortness of breath.
Spirometry	There is a small risk of wheezing, shortness of breath and lightheadedness. If you have recently had an air leak from your lungs (pneumothorax) or you are coughing up blood, you should tell your study doctor or study nurse to help them to decide if you should do spirometry.
Questionnaires	Some questions may feel too personal or make you uncomfortable. If this happens, please talk to the study team about why that question is being asked. If you are still uncomfortable, you may choose not to answer.
Electronic Questionnaires	We will work to make sure that no one sees your survey responses without approval. But, because we are using the Internet, there is a

	chance that someone could access your online responses without permission. In some cases, this information could be used to identify you.
Confidentiality	Being in any research study has the risk of loss of privacy or confidentiality. Below tells you how your information will be protected.
Randomization	There may be risks related to randomization to the study intervention. If you randomize to one type of antibiotic, there may be a risk of having an early relapse of your exacerbation. If you randomize to two types of antibiotics, there may be additional risks (like drug toxicity). These are potential risks seen in standard of care and if you have concerns discuss them with your research doctor.

WHAT IF WE LEARN NEW INFORMATION DURING THE RESEARCH?

You will be told about new information that might change your decision to stay in this study. You may be asked to sign and date a new consent form if this occurs.

WHAT ARE THE BENEFITS THAT CAN HAPPEN FROM THIS RESEARCH?

Potential Benefits for You:

Your condition may improve, stay the same, or get worse. If assigned to the IV tobramycin and Beta-lactam arm you may benefit from receiving a more effective treatment regimen. If assigned to the Beta-lactam alone arm you may be getting an equally effective treatment without exposure to an aminoglycoside.

Potential Benefits for Others:

Although you may not receive direct benefit from this study, the information and samples collected from this study may benefit others who have CF in the future.

WHAT ARE MY OTHER OPTIONS?

Taking part in research is voluntary. You do not have to be in this research study in order to receive patient care for your pulmonary exacerbation. If you decide not to take part in this research study, your doctor will treat your pulmonary exacerbation using antibiotics. Typically, the antibiotics prescribed to treat *Pa* pulmonary exacerbations are beta-lactams and tobramycin.

WILL IT COST ME ANYTHING EXTRA TO BE IN THE RESEARCH STUDY?

Tests and procedures that are done only for the study will not be billed to you or your insurance company. You or your insurance will be billed for tests and treatments that are done for your usual medical care. All of your insurance company's usual rules would apply.

If you agree to complete the ePRO questionnaires using the Medidata application, there may be fees for text messages and data usage which will not be reimbursed.

WILL I BE PAID TO BE IN THIS RESEARCH STUDY?

«Compensation»

You will be paid for your time and effort. You may receive up to $202.50 $232.50 to cover the time it takes for the study visits and doing the electronic questionnaires. You will not be paid for any missed visits/procedures.

The following amounts will be paid for each completed visit:

Visit #	**Payment Amount**
Visit 1	$ 90.00
Visit 2	$ 60.00
Visit 3 Phone Call	$ 30.00
Completion of electronic questionnaires (up to 3 total)	$ 7.50
Day 14 Urine and Sputum	$ 30.00

If you consent at Visit 1, but you do not meet the requirements to be in the study, you will not come in for any additional visits and will only be paid $30 for Visit 1.

You would receive reimbursement for out of pocket costs that may occur because you are taking part in this study, such as parking, mileage (at the current federal business mileage rate), tolls, or childcare for visits that are not part of your standard CF care.

For sites using Greenphire for compensation:

A company called 'Greenphire' will manage travel reimbursement and a ClinCard, which is a debit card, will be provided to you at Visit 1. When you complete a visit, the amount outlined in this Informed Consent Form will be automatically approved and added onto your ClinCard usually within 2 days. The study staff will provide you with additional information about how the ClinCard works. In order for Greenphire to be able to reimburse you using the ClinCard, Greenphire will collect the following information about you: your name (required), birth date (required), address (required), social security number (required for IRS reporting) and contact details (cell phone number and/or email address – optional). By choosing to use the ClinCard service you are authorizing the release of this information to Greenphire.

The payment for the questionnaires may not happen until the end of the study.

Greenphire has safeguards to protect the confidentiality of your personal information. Your personal information will not be shared by Greenphire with the study sponsors or their representatives or sold, used, or distributed for any other purpose. Your information will be kept only as long as necessary. You can change or remove your information at any time by contacting the study team or Greenphire at notices@greenphire.com.

Payment received for study visits is considered taxable income. If this payment is more than $600.00 in any one calendar year Greenphire is required to report this to the Internal Revenue Service (IRS). For this purpose Greenphire requires your social security number. The study sponsor will not have access to your social security number. Income will be reported using a 1099 (Miscellaneous Income) form. A copy will be sent to you and to the IRS. Please be aware

that all reimbursements such as parking, mileage, tolls, or childcare do not count towards the $600 limit and will not be taxed as income.

If you are currently receiving supplemental security income (SSI), Medicaid, or Medicare, because you have CF which is a rare disease, you can receive up to $2,000 per calendar year as payment for study participation without losing your benefits or affecting your continued eligibility for these benefits. Please ask your study team for details.

WHO IS PAYING FOR THIS STUDY?

CFF is paying for this research study.

WHAT SHOULD I DO IF I THINK THAT I HAVE BEEN INJURED AS A RESULT OF THIS RESEARCH?

If you were injured as the direct result of this research study, the study site would provide treatment. We would refer you for treatment if needed. No funds have been set aside for this treatment. You or your insurance company would be billed for the treatment.

It is important that you tell the study doctor, if you think that you have been injured as a result of taking part in this study. You can call him/her at the telephone number listed on page one of this consent document.

If you go to the Emergency Room or to another hospital or doctor, it is important that you tell them that you are in a research study. If possible, you should give them a copy of this consent form.

If medical costs are incurred, your insurance company may be billed. The study center listed on page one of this consent form makes no commitment to provide free medical care or other compensation for injury or illness resulting from your participation in this study. By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

CAN I CHANGE MY MIND?

Your participation in this study is voluntary. You may decide not to participate. If you join the study, you can decide to stop at any time for any reason. Any decision you make will not result in any penalty or loss of benefits to which you are entitled.

The study doctor or the sponsor may stop your participation in the study at any time. Your study doctor will explain why. Reasons may include that the study doctor thinks it is in your best interest, it is not safe for you to stay in the study, or that the sponsor decides to end the study early.

If you decide that you want to stop your intervention assignment, you are encouraged to continue participating in the study up to the last study visit (without following the intervention assignment). The visits and procedures would stay the same.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

If you take part in this study, we will make every effort to keep your information confidential.

We will store all of your research records in locked cabinets and secure computer files. We will not put your name on any research data. Instead, we will label your information with a study number. The master list that links a person's name to their study number is stored in a locked cabinet or on a secure computer file.

Medidata (the company that makes the questionnaire application) will not share your personal information such as name, email address, and mobile phone number. The only data shared with the study sponsors are your responses to the questionnaires. Any data entered into the application is encrypted.

The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name.

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. If results of this research are published, we would not use information that identifies you.

We would only use your information for research. The following are some reasons that we may need to share the information you give us with others:

- If it's required by law.
- If we think you or someone else could be harmed.
- Sponsors, government agencies or research staff sometimes look at forms like this and other study records. They do this to make sure the research is done safely and legally. Anyone who reviews study records would keep your information confidential.
    - Agencies or sponsors that may look at study records include:
        - United States Food and Drug Administration (FDA) and Government Agencies
        - Study Sponsor and their representatives including: the Cystic Fibrosis Foundation and the CFF Therapeutics Development Network Coordinating Center
        - Hospital Auditors
        - Institutional Review Board (IRB) and others responsible for watching over the safety, effectiveness, and conduct of the research.

If you join this study, we would put information about this study in your medical record. We do this because the research study involves patient care.

If you join the study, we will keep your information confidential as provided by law.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;
- The Study Doctor's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;

Please contact the Study Doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, 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: Pro00064313.

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.

CONSENT TO PARTICIPATE IN THE STUDY FOR ADULT PARTICIPANTS AND PARENT/LEGAL GUARDIAN OF MINOR PARTICIPANTS

I have had enough time to consider the risks and benefits of taking part in this study, to ask questions, and to discuss the study. My questions have been answered to my satisfaction.

I understand that my participation is voluntary and that I am free to stop taking part at any time and without my medical care being affected.

I will receive a copy of this signed and dated Consent Form and any information sheets to keep.

I agree to take part in this study.

_____

Signature of Participant Date

_____

Printed Name of Participant

If the participant is younger than the age of majority:

_____

Signature of Parent or Legal Guardian Date

_____

Printed Name of Parent or Legal Guardian

STATEMENT OF ASSENT FOR PARTICIPANTS AGE 12 TO AGE OF MAJORITY

I would like to be in this study.

_____

Signature of Participant Date

_____

Printed Name of Participant

Researcher's Signature

I attest that I have explained the purpose, tests, procedures, benefits, risks and the use and disclosure of medical record information. The participant has had the opportunity to consider their options in response to the information provided. I verify that sufficient time has been allowed for questions and exchange of information.

_____

Signature of Person Conducting the Informed Consent/Assent Discussion Date

_____

Printed Name of Person Conducting the Informed Consent/Assent Discussion

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR MEDICAL RECORD INFORMATION

During your participation in this research study, the study doctor and study team will collect or create personal health information about you and record it on study documents. The study doctor will keep this personal health information in your study-related records (that we will refer to as "your study records"). Your study records may include other personal information (such as social security number, date of birth, etc.), which could be used to identify you. Health information that could identify you is called "Protected Health Information" (or "PHI").

Under federal law (the "Privacy Rule"), your PHI that is created or obtained during this research study cannot be "used" to conduct the research or "disclosed" (given to anyone) for research purposes without your permission. You may not participate in this study unless you give your permission to use and disclose your PHI by signing and dating this Authorization. By signing and dating this Authorization form, you are agreeing to allow the study doctor and study team to use your PHI to conduct this study.

Confidentiality – Will My Medical Information Be Kept Private?

Your medical records and information about you are protected by privacy standards and will be kept as confidential as possible within the limits of the law. Every reasonable effort will be made to protect your confidential information, but this cannot be guaranteed. Information from which you may be personally identified will be maintained in a confidential, secure location at the research clinic, accessible only by authorized members of the study team, and will not be disclosed to third parties except as described in this authorization form, with your permission, or as may be required by law.

The study team will assign a code number to your records, which means that you will not ordinarily be identified in the records sent to the sponsor. The sponsor may, however, look at your complete study records that identify you. In addition, the sponsor may visit the study site to oversee the way the study is being conducted and may review your PHI during these visits to make sure the information is correct.

As part of this research, you are required to use mobile device apps. While using these, information about you may be collected and shared with the researchers or people outside of the study. This data might include personal health information. A complete description of the data collection and sharing for an app

can commonly be found in the Terms of Use, End User License Agreement, or Privacy Policy associated with the app. If you would like to read these documents, request a copy or instructions about how to access this information from the study doctor.

While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your rights if you are harmed as a result of your use of the apps, you do not release the study doctor, sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research participant.

Medidata (the company that makes the questionnaire app) will not share your personal information such as name, email address, and mobile phone number. Any data entered into the apps is encrypted (which means that the data is scrambled so only people with a secret code can read it). The only data shared from the Medidata app with the study sponsors are dates and your responses to the questionnaires.

Will the study require any of my other health care providers to share my health information with the researchers of this study?

As a part of this study, the researchers may ask to see your medical records from your other health care providers.

Who May Disclose My Medical Record Information?

Only the study team may disclose your medical record information.

Who May Receive and Use My Medical Record Information?

In addition to the study team, the following individuals may receive your medical record information related to your participation in this research study:

- The sponsor of this study and anyone working on behalf of the sponsor to conduct this study (referred to as "the sponsor"). This includes the CF Therapeutics Development Network Coordinating Center (Seattle Children's which is coordinating the study) and Medidata
- The Institutional Review Board ("IRB") at the study site
- In unusual cases, the study team may be required to release your medical record information in response to an order from a court of law
- Authorized representatives of the United States Food and Drug Association (FDA) and other regulatory agencies

- Authorized representatives of the study site or other associated health care providers may have access to your medical records to (1) fill orders made by the study team for hospital and health care services (such as laboratory tests, diagnostic procedures); (2) address correct payment for tests and procedures ordered by the study team; and (3) for internal hospital operations (such as quality assurance)

These disclosures also help ensure that the information related to the research is available to all parties who may need it for research purposes.

Except for the disclosures described above, your PHI will not be shared with others unless required by law. If your PHI is shared with the parties listed above and/or to others who are not required to comply with the federal law, your PHI will no longer be protected by this law and could possibly be used or disclosed in ways other than those listed here.

Why Will This Information be Used and /or Given to Others?

The sponsors and individuals listed above will use your information to complete the research, evaluate the results and check to make sure the study is done properly.

If results of this research are published or presented at a scientific meeting, we would not use information that identifies you.

Can I Access My Medical Record Information?

You have a right to see and make copies of your PHI. You are agreeing, however, by signing and dating this document, not to see or copy some or all of your PHI until the sponsor has completed all work related to this study. At that time, you may ask to see your records.

Can I Withdraw Authorization to Use My Medical Record Information?

This Authorization will expire 50 years from the date you sign and date it unless you revoke (cancel or withdraw) it sooner.

You have a right to revoke your Authorization at any time. If you revoke it, your PHI will no longer be used for this study, except to the extent the parties to the research have already taken action based upon your Authorization or need the information to complete analysis and reports for this research. To revoke your Authorization, you must write to the study doctor, stating that you are revoking your Authorization to Use and Disclose Protected Health Information. If you revoke this Authorization, you will not be allowed to continue to be in this study.

I authorize the use and disclosure of my medical information collected during this study and information contained in my medical records.

_____

Signature of Participant Date

_____

Printed Name of Participant

If the participant is younger than the age of majority:

_____

Signature of Parent or Legal Guardian Date

_____

Printed Name of Parent or Legal Guardian