INFORMED CONSENT FORM AND
AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR MEDICAL RECORD

Standardizing Treatments for Pulmonary Exacerbations (STOP360)

DETAILED STUDY INFORMATION

What will happen if you join the study?

The study will take approximately 6 hours of your time over 6 weeks. This includes 2 in-person visits and one phone call. The procedures done at the study visits will help us answer the research question.

At the first visit, a computer will assign you by chance to get an IV beta-lactam alone or both a beta-lactam and an IV aminoglycoside for approximately 14 days. You and your doctor will know which group you are in. The antibiotic(s) can be taken at home or in the hospital.

You will be asked not to take oral or inhaled antibiotics that work against Pseudomonas until after your second visit in about four weeks. Examples include ciprofloxacin and tobramycin (TOBI).

Your doctor will be monitoring your progress while you're on IV antibiotics. Your doctor can change IV antibiotics if they think you're not responding well enough.

You will also fill out electronic questionnaires using a phone app twice: one week and two weeks after you enroll. You will also have a phone call in six weeks. Below is the detailed list of what will happen during the study:

Study Procedures	**Enrollment** Visit 1	**Weeks 1 and 2**	**Week 4** Visit 2	**Week 6** Phone Call
Medical and Personal Information	X		X	X
Paper Questionnaires	X		X	
Electronic Questionnaires		X		X
Physical Exam, Height, Weight	X		X	
Pulmonary Function Test	X		X	
Urine Collection	X		X	
Sputum Collection	X		X	

Pregnancy Test	X			
Approximate time	**2-3 hours**	**5 mins**	**1-2 hours**	**30-60 mins**

- **Medical and Personal Information**: We will review your medical chart and collect information from you like your sex at birth, date of birth, and race. We will also ask about your medical history including illnesses and medications.
- **Paper Questionnaires**: You will be asked questions about your health, quality of life, ringing in your ears, and problems with balance.
- **Electronic Questionnaires:** You will be asked to answer questions about your health and quality of life using an app that you download on your own cell phone or tablet device. The questionnaire app is made by the company Medidata. The app will require you to enter your name, email address and phone number, and to agree to its terms of use. If you do not want to or cannot download the app, you can still be in the study. You will receive text messaging reminders to complete the questionnaires.
- **Physical Exam:** You will have a physical exam including height and weight.
- **Pulmonary Function Test:** Your lung function will be measured. You may be asked to take a bronchodilator such as albuterol before doing the pulmonary function test.
- **Urine Collection**: A specimen will be collected and stored for future research.
- **Sputum Collection**: If you can cough up sputum, a specimen will be collected and stored for future research.
- **Pregnancy Test**: All people who can potentially become pregnant will have a pregnancy test at the first study visit. The test must be negative at the beginning of the study because the treatment options in this study may not be appropriate during pregnancy.
- **Routine blood test results**: If blood tests are done as part of your clinical care, we will record the results from those tests.

What are the potential benefits to taking part in the study?

Potential Benefits for Others: Learning which antibiotic approach is better may benefit people who have CF in the future.

Potential Benefits for You: The usual approach to treating exacerbations is to use two antibiotics. If assigned to the beta-lactam alone, you may be getting an effective treatment without exposure to the risks of an aminoglycoside.

What are the potential risks, side effects or discomforts of being in the study?

The main risk in this study is that if you get a beta-lactam alone, you may not improve as much as if you get both antibiotics.

Antibiotics: Both types can cause an allergic reaction (including a severe allergic reaction with swelling in the throat or difficulty breathing). Both types also have their own specific risks.

Antibiotics	**Associated Risks**
Aminoglycosides (like tobramycin)	The risks include kidney injury, hearing loss, ringing in the ears, balance problems, and, rarely, muscle weakness. These problems may develop gradually after repeated use but can be permanent and are sometimes severe.
Beta-lactams (like ceftazidime)	The risks are temporary and include abdominal pain, diarrhea, nausea and vomiting, decreased white blood cells, decreased platelets, and skin rashes.

Study Procedures: There are some minimal risks related to study procedures. The study procedures are the same as those done at standard clinic visits and have the same risks.

Procedure	**Associated Risks**
Sputum Collection	Coughing up sputum may cause temporary shortness of breath.
Pulmonary Function Test	Pulmonary function testing can cause temporary wheezing, shortness of breath and lightheadedness.
Questionnaires	Some questions may 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 do not have to answer the question.
Questionnaire app	Medidata is a separate company from our study team and makes the app. Information about how Medidata uses your information is found in their terms of use. There could be privacy risks associated with using the app. The app will take up space on your phone. Read the privacy notice if you'd like to learn more.
Sharing personal information	There is a small chance that someone could access your study data, including your personal information, without permission.

The CFF Data and Safety Monitoring Board will be looking at the study data as the study is being conducted to monitor safety.

What should you do if you think you have been injured because of this study?

If you think you are injured as the direct result of this study, you should call the study doctor. The study site will provide treatment or refer you for treatment if needed. Your insurance company would be billed for the treatment. The study site makes no commitment to provide free medical care or other compensation for injury from your participation in this study. But

you will not lose any of your legal rights or release anyone involved in the study from responsibility for mistakes.

Are there any costs to you for taking part in this study?

You will not be billed for procedures done only for research. Your insurance company will be billed for your usual medical care including antibiotics and related tests. You may have fees for data usage to complete the questionnaires using the Medidata app

Will you be paid to take part in this study?

You will be paid up to $202.50 to cover the time and effort it takes to complete study visits and electronic questionnaires. We will give you separate information about how you will be paid. You will be paid after each completed activity as follows:

Enrollment Visit	$90
Week 4 Visit	$60
Week 6 Phone Call	$30
Completion of electronic questionnaires (up to 3 total)	$7.50 (up to $22.50)

1. The payments from this study may be taxable. Study sites are required to report to the IRS payments totaling $600 or more made to anyone in any one year.

2. If you are currently receiving supplemental security income (SSI), Medicaid, or Medicare, 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 and let your study team know if you have any questions or concerns about this.

Your study-related expenses such as parking, mileage (at the current federal business mileage rate), tolls, meals, or childcare for visits that are not part of your standard CF care will also be reimbursed if you provide receipts or documentation.

If you agree to join the study, but are found to be ineligible, you will be paid $30.

What if you don't join this study?

You do not have to be in this study to be treated for your pulmonary exacerbation. In this case your doctor will treat your pulmonary exacerbation using antibiotics. Typically, these are beta-lactams and tobramycin.

Can you stop being in the study?

You can decide to stop at any time for any reason. If your antibiotics are changed while you are enrolled in the study, we would ask you to complete the visits and procedures.

What if we learn new information that might change your decision to be in this study?

You will be told about new information. You may be asked to sign a new consent form if this occurs.

Will you be able to learn about the results of this study?

Once the study is completed, we will let you know how to get a summary of the results.

How many people will take part in this study?

About 730 people with CF will take part in this study at approximately 70 hospitals and clinics around the United States, Canada, and Europe.

Who is paying for this study?

The Cystic Fibrosis Foundation (CFF) is paying for the study.

How will your information be kept private?

We will label your information with a study number. The master list that links a person's name to their study number will be stored separately. We will store all your research records on secure computers.

Clinical data collected about you during the study will be included in your medical record because the research involves your care.

Medidata will be collecting your name, email address, and mobile phone number but will not share your personal information. The only data shared with the study team are your responses to the questionnaires. Data entered into the application is encrypted.

There are some reasons why we may be required to share the information you give us with others. The most common reason for this is to make sure the research is done safely and legally. This is explained more in the Health Insurance Portability and Accountability Act (HIPAA) authorization.

We will not use information that identifies you if this research is published.

How will your data and specimens be used for future research?

Specimens: Your specimens will be stored in the CFF specimen bank to support future research. We will keep your specimens indefinitely or until they are used up.

Study data and stored specimens: These may be shared with other researchers for future research to help us understand CF better. If this happens, the information will be coded so that the researchers will not be able to identify you.

We will only share your data or specimens with researchers who have approval from their Institutional Review Board (IRB) and the CFF. For-profit companies will need the same approval before any data or specimens will be given to them. You will not be told that your data or specimens are used for future research, and you will not be given individual results. If any new therapies, products, or procedures are developed from your data or specimens you would not receive any money.

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Results from research studies using your data or specimens may be published in medical journals or presented at scientific meetings, but your name and other identifying information will not be used.

CFF Patient Registry Data: You previously enrolled in the CFF Patient Registry, a database that contains information about the clinical care of people with CF (such as hospitalizations and medications).

We will use your CFF Registry identification number (ID) to link your clinical care information in the registry (past, present and future) to your stored specimens and data from this research study.

Your CFF Registry ID may also be used to link data from this study with other studies that you enroll in.

What if you change your mind about sharing your data or your specimens?

If you change your mind during the study, 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 data and specimens will no longer be shared but what has been shared with researchers will continue to be used.

Who do you contact about this study?

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study. During the study, if you experience any medical problems, experience a research-related injury, or have questions, concerns or complaints about the study, please contact the Study Doctor at the telephone number below.

Study doctor:	**<<PI full name>>**
Telephone:	**<<ICF phone number>>**
Address:	**<<PI locations>>**
Principal Investigators:	Patrick Flume, MD (Medical University of South Carolina) Christopher H. Goss, MD MSc (University of Washington)

If you have any questions about your rights as a research subject, contact the IRB at:

- **Mail**: Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- **Phone**: 877-992-4724
- **Email**: adviser@advarra.com

Please reference Pro00064313 when contacting the Study Subject Adviser

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
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 Consent Form.

I agree to take part 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.

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Signature of Person Conducting the Informed Consent Discussion Date

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Printed Name of Person Conducting the Informed Consent Discussion

ADMINISTRATIVE INFORMATION

PRINCIPAL INVESTIGATORS FOR THE STUDY **NOTE TO SITES: Fill in the information below with information that is specific for your site.**	
Site Name:	
Site Principal Investigator:	
Site Principal Investigator Contact:	

Site Study Coordinator:	
Site Study Coordinator Contact:	

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.

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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