CONSENT TO TAKE PART IN A RESEARCH STUDY

If the participant/LAR cannot read this form (like when they cannot see or read well), then the study doctor may read this form to the participant/LAR as written. When this form is read to a participant/LAR, an impartial witness must be present, and the accompanying IRB approved short form must be signed by the participant/LAR and witness.

STUDY TITLE: Studying the Presence of CFRD Complications with Thoughtful Recruitment (SPeCTRuM)

STUDY DOCTOR'S INFORMATION

Site PI Name:
Site Name:
Mailing Address:
Emergency (24-hour) Number:
Study Phone:

SUMMARY

In this form, when it says "you" it is referring to you as the participant if you are an adult, or to the person under your care that would be in the study if you are a legally authorized representative (LAR). An example of an LAR is a parent reviewing the information for their child, a minor, to be in the study. In this case, "you" means "your child."

Informed consent is the process that tells you about what is involved in a research study. It tells you about the study, study procedures, and study treatments (if the study has study treatments). It tells you about how study procedures are done and what side effects could happen. This process usually involves reading a form like this one, someone on the study team talking to you about the study, and getting your questions and concerns addressed. The goal is that you have all of the information you need so that you can decide if you want to participate in the study.

You do not have to be in this study. You can stop being in the study at any time. If you decide not to be in this study, there will not be any penalty or loss of any benefits that you normally get. You should read and discuss all of the information in this consent form with the study doctor or other study team member. You can ask for a copy to share with other people to help you decide. Do not agree to be in this study unless all of your questions have been answered. Please take as much time as you need.

STUDY OVERVIEW

- This study is being done to learn how common health issues like high blood pressure, vision problems, and kidney disease are in people with cystic fibrosis-related diabetes (CFRD). About 200 people at about 20 CF Care Centers in the United States will be in this study.
- This is a data collection study. You will not be asked to take a drug or do any treatment for this research study.
- You will be asked to be in this research study for 1 or 2 in-person visits, to wear a few different devices, and to complete questionnaires about diabetes and diabetes treatment. The number of times you need to come in will be based on how your procedures are scheduled. The study team will talk with you about this. The device you would wear the longest is a continuous glucose monitor (CGM). You will be asked to wear the CGM for up to 10 days. There may be some devices that cannot be worn or used at the same time. It may take up to four weeks to finish all the study tasks.
- The most likely risks to you are:
    - a possible loss of privacy or confidentiality
    - mild soreness or irritation from blood sample collection
    - Some discomfort and trouble seeing that usually lasts less than about four hours after getting your eyes dilated.
- You may receive no direct benefit from being in the study. People who take part in this research study will add new knowledge that may help other people with CFRD.
- If you do not participate, you will continue to receive your standard care and treatment of CF and CFRD.

WHO IS DOING THE STUDY?

This research study is being paid for by the Cystic Fibrosis Foundation. The Jaeb Center for Health Research will use the funding to organize the study. Your study doctor and clinic staff will use the funding to carry out this study. The study doctor's contact information is listed on the first page of this form.

WHY IS THIS STUDY BEING DONE?

You are being asked to take part in this research study because you have had cystic fibrosis-related diabetes (CFRD) for at least five years. The goal of this study is to learn things that may help people with CFRD.

Many people who have CF are likely to develop CFRD by the time they are an adult. This study is being done because not a lot is known about the chance of having health problems caused by CFRD. Diagnosis and treatment guidelines for health problems caused by CFRD are from studies of Type 1 and Type 2 diabetes. CFRD is different than Type 1 and Type 2 diabetes, so we need information specific to CFRD. We would like to learn more about these health problems. This study will give researchers information to help with future research.

WHO CAN PARTICIPATE IN THIS STUDY?

About 200 people will take part in this study at up to 20 different CF Centers across the United States. In general, to take part in this study, you must:

- Be age 12 or older
- Be diagnosed with cystic fibrosis
- Be diagnosed with cystic fibrosis-related diabetes five or more years ago from today
- Understand this consent form

Also, you must not:

- Have had a transplant
- Know that you are pregnant

The study team will review more health-related requirements with you.

WHAT WILL HAPPEN IN THIS STUDY?

You will be asked to do things you would normally do as part of your standard CF and CFRD care. Examples are having your vitals taken, fasting at least 8 hours overnight for a blood draw, giving a urine and stool sample, and a retinal exam. The retinal exam involves taking pictures of the back of your eye and an optometrist may look in your eyes. You will also have the option of doing an extra part of the study which would be getting an ultrasound on your neck and thigh arteries.

You can do some study procedures while at home. We will ask you to fill out questionnaires, complete a daily insulin dairy for three days if you use insulin, complete a food diary for three days, wear a physical activity tracker, and wear a blinded continuous glucose monitor (CGM). If you use a Dexcom CGM to manage your diabetes, we are able to use your data so that you do not need to wear a blinded CGM. If you do not normally wear a CGM to help manage your diabetes, the CGM you wear will be blinded meaning you will not be able to see the glucose measurements from the CGM. You may be asked if you want to wear a blood pressure monitor for 24-hours. You would return the study devices to your study team once you are finished. In-office activities may be done over one or two days. You and the study team will decide what schedule is best for you. You may be able to start some study procedures if you sign the consent form while at the study care center. These would be things like:

- Having the CGM placed

- Begin use of a physical activity tracker that will have an application that may be loaded to your phone
- Getting the study supplies for things you can do at home.

A visit would be scheduled for later to get your blood drawn or, if you are already fasting, we can potentially draw the blood at this visit.

Some of your information may also be collected from the CF registry if you have a CF registry ID number.

Collection of Information for Geocoding

As part of this study, we will be collecting either your full address of where you live most of the year or the zip code only. We will use this information for something called *geocoding*, which means turning an address into map coordinates (like latitude and longitude). This helps us explore how where people live might be related to their health. For example, we may look at things like access to food, transportation, or healthcare in your area. These are called *Social Determinants of Health (SDoH)*—factors that can affect a person's health beyond just medical care.

We will also use tools developed by the National Institutes of Health (NIH) to look at other SDoH, such as:

- English language proficiency
- Food security
- Access to medications

Our goal is to better understand the overall health and health challenges of people in this study, and how those might be connected to where they live.

Providing your full address is optional, you can choose to only share your zip code. This information will not be linked with personal information like your name, but it will be linked to the other data collected for this study through a study ID that is created for you.

The table that follows shows what will happen while you are in this study:

	Estimated Time to Complete	Where to Complete
HISTORY, INTERVIEWS, AND QUESTIONNAIRES		
Informed Consent	30 minutes	Care Center
Questionnaires	1.5 hours	Care Center or Home
Review Your Medical History, Medications, and brief interview with study team	1 hour	Care Center
ASA24	3 days	Home
PROCEDURES		
Height/Weight/Heart Rate/Blood Pressure/Temperature	10 minutes	Care Center
Collection of samples for central and local labs, and biorepository ▪ Stool ▪ ~1 and 3/4 tablespoons of Blood ▪ ~ 3/4 tablespoons Urine	20 minutes	Care Center or Home Care Center Care Center
Dexcom G6Pro CGM (or Dexcom G6/G7 if already used for clinical care)	Up to 10 days	Home
Physical Activity Tracking	3 days	Home
Eye Imaging	2 hours	Clinic
Insulin Diary	3 days	Home
OPTIONAL SUB-STUDY PROCEDURES		
Pulse Wave Velocity and Pulse Wave Analysis	30 minutes	Clinic
24-hr Blood Pressure	1 day	Home

OPTIONAL ACTIVITIES

The activities below are extra parts of the study. They are optional. You are not required to participate in these activities if you do not want to. You can still be in the main study. Not all CF centers will be participating in these extra activities. The study team will tell you if their center is participating in these activities. You may choose to participate in one, all, or none of these activities.

Pusle Wave Velocity (PWV) and Pulse Wave Analysis (PWA)

An ultrasound probe and cuff will measure how fast your blood flows between your carotid artery in your neck and femoral artery in your thigh. You will lie on an examination table for the test, which should last about 30 minutes. This test is painless and does not involve needles.

You may not be able to do this sub study if you have had a mastectomy or have been diagnosed with:

- irregular heart rate
- carotid artery disease (a buildup of plaque in the arteries)
- aortic stenosis (an issue with a valve in the heart that limits blood flow)
- peripheral artery disease or leg artery disease (an issue with the arteries that limits blood flow to the legs)
- arteriovenous shunt (issues with an artery and vein that become connected which causes problems with blood flow)
- or other blood flow issues

The study team will talk with you about these conditions and look at your medical records to make sure you can do this part of the study.

If you have a history of hypotension, the study team will ask that you move slowly as you stand-up after the procedure.

24-Hour Blood Pressure Monitoring

If you choose to be part of this sub-study, you will wear a blood pressure cuff on your bicep (the upper part of the arm) for about 24 hours. You should wear the cuff for the entire day during all your activities including sleep. The cuff will fill up with air and become very tight to check your blood pressure. It will do this every 15 minutes during the day and about every 30 minutes at night.

The machine that connects to the cuff is worn on a belt around your waist when you are up and moving. It can be put on a table when you are sitting or sleeping. You may feel some mild discomfort while the cuff takes your blood pressure. You may also be woken up throughout the night while you are trying to sleep. You will give back the cuff and machine to the study team either by mail or in person. If you need to mail it in, we will give you a box and label to send it back to your study team.

Specimen Banking

“Specimen banking” is storing specimens that can be shared with other researchers. We will ask you if you want to bank your specimens (blood, urine, and stool). If you agree, we will send some of the sample we collected at the study visit to be banked for future research use. The specimens may be used to study genes related to CFRD, but whole genome sequencing, like identifying your DNA, will not be done as part of this research.

The Cystic Fibrosis Foundation (CFF) has a specimen bank that keeps specimens from CF research studies. The specimens in the bank will be used to learn more about CF. The research that will be done with your samples will not be used to identify you. The CFF will:

- label your samples with a barcode. Future researchers looking at the specimens will not be able to know who you are.
- store your samples at a specimen storage company contracted by the CFF.
- keep your samples forever or until they are used up.
- keep a list linking the barcodes on your samples to your identifying information (such as initials). The Jaeb Center for Health Research will also have this list. It is kept in a separate secure database protected with passwords.
- ensure that if your health information is shared that it will not have any information that could identify you.
- only share your specimens and data with researchers who have approval from their Institutional Review Board (IRB) and the CFF. For-profit companies may also ask to use the samples. They will need the same approval before any samples and/or data is given to them.
    - If you want more information about the CFF Biorepository, please visit their website:
        - https://www.cff.org/researchers/cf-foundation-biorepository#clinical-sample-acquisition-process.
- ensure that published or presented results from research studies using the specimen bank do not identify you.
- not be able to give you the results from the future research done using your specimens.
- NOTE: You will not get any money from any new therapies, products or procedures created from studying your samples.

CF FOUNDATION PATIENT REGISTRY DATA

The Cystic Fibrosis Foundation’s (CFF) Patient Registry is an archive that holds data about the clinical care of people with CF. People who join the registry get a unique identification (ID) number to label their data. For the SPECTRUM Study we will get your ID number if you have one. This ID will help us link your registry data (past, present and future) to your banked samples and data from SPECTRUM-CF.

Current and future studies or databases may use your registry ID to link to data from this study. Data added from this study to the registry may be used for current and future research.

Please tell the study team if you change your mind and no longer want to share your information from the CFF Registry. If you change your mind after the study is over, you may email the CFF at reghelp@cff.org. Your CFF Registry ID would no longer be used to link your future registry data to this study. Any registry data that was linked to this study would still be used and cannot be removed. This includes data linked with your banked samples or data already shared with other researchers.

WHAT ARE THE RISKS OF THIS STUDY?

This is a minimal risk study. The risks are like what you would have if you were not in the study. You can decide to take a break or stop taking part in the study at any time.

Confidentiality

This study will be collecting some information about you that includes identifiable, personal information, like your date of birth. The study has plans in place to protect that information. There is a chance that someone may see some of this information when they are not supposed to have access. Please see the “How will my information be protected and kept confidential” section below for more information.

The more likely known risks

- Questionnaires: Questions will ask about
    - Your education, health insurance, access to resources like housing, food, and medical care
    - Your personal attitudes, feelings, and behaviors related to cystic fibrosis, diabetes, and diabetes technology
    - Your diet, including foods, drinks, and supplements
    - Symptoms of nerve damage related to diabetes

  There are no physical risks, but you might feel momentary embarrassment or discomfort. You do not need to answer any questions that make you too uncomfortable.
- Continuous glucose monitor (CGM) sensor placement: You may feel some pain (like a pinprick) when the CGM sensor is placed under your skin. In rare cases, the skin at the sensor location can become irritated, infected, or may bleed. There is a small risk of discomfort at the placement site. You can remove the sensor if there is any sign of bleeding, discomfort, skin irritation or infection. Sensor tips may break off under the skin in very rare cases.

- Overnight fasting: Most people do not have medical problems when fasting. You may get a headache, become lightheaded, or have an upset stomach from fasting. Some people have medical conditions that limit their ability to fast. If your doctor has told you not to fast, or if your bloodwork indicates you should not fast, you should not fast for this study. You can still give a sample of blood even if you are not able to fast. There are some blood tests we can still do.
- Blood draws: Anytime you have your blood drawn you may have bruising, discomfort, and bleeding. These are usually mild, and more common than other problems like fainting or infection. Fainting and infection are possible but unlikely.
- Urine sample: You will get your urine sample in a private restroom at your care center. You may have momentary embarrassment.
- Stool collection: You will collect your stool in a private restroom at your care center or at home. You may have momentary embarrassment.
- Vitals: There are no physical risks but you might have momentary embarrassment or discomfort. The exam is like those that you get for routine medical care. When blood pressure is taken, the blood pressure cuff may cause discomfort or bruising to the upper arm.
- Eye exam: Dilating drops may be used to get the images of your eye. You might have a mild burning sensation, blurry vision, sensitivity to light and trouble focusing until the dilating drops wear out. The camera or imaging machine used for the eye exam might also cause some discomfort due to bright flashes of light that are needed to take pictures of your eyes.
- Pubertal assessment: If you are less than 18 years old, you will be asked to complete a self-administered pubertal assessment. You will get a form with drawn images and text to help you do the assessment. You may have momentary embarrassment. The responses to these questions will be confidential and protected with your other collected health information.

Optional Procedures

- 24-hour Blood Pressure measurement: You may have temporary numbness/tingling, or bruising in the arm, or become distracted or uncomfortable. You may wake up when measurements are taken at night.
- Pulse Wave Velocity and Pulse Wave Analysis: You may have minor discomfort over the area where the ultrasound probe touches your neck. You may also have discomfort on your thigh where the “blood pressure cuff” is.

Unknown Risks

It is always possible that anyone trying something for the first time may have an allergic reaction. Also, there may be additional risks from the study that are not known. If we find out that there are any new risks, you will be told about them. You will be able to decide if you want to continue in the study based on the new information.

As part of this study, you will undergo many tests to collect information about your health (e.g., eye exam, blood work, etc.). There is a possibility that the researchers will notice an abnormality in the results of one of these tests. This is called an “incidental finding.” Although the study team may not have enough information to make a diagnosis if they see an incidental finding, we will let you know that one was found. An incidental finding may cause you to feel anxious, but we will help you understand what was found so you can give information about this incidental finding to your primary doctor, or we can refer you to an appropriate doctor for further evaluation.

Genetic Information

The study may collect your blood samples to learn more about how diseases occur more in some families than in other families. It is possible that others could misuse this information.

A federal law called the Genetic Information Nondiscrimination Act (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you because of your genetic information. This law does not protect you from genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you from discrimination if you have already been diagnosed with a genetic condition.

Whole genome sequencing, like identifying your complete DNA, will not be done as part of this research.

Please discuss the risks with your study doctor or any other health care provider.

OTHER DATA COLLECTION AND MESSAGING INFORMATION

Activity Data

You will use an Actigraph wristband to track your activity over three days from home. This wristband is similar to a Fitbit. You will return the wristband to the study care center at your visit or by mailing it to them. If you need to mail it, you will be given a pre-paid label. The study team will upload the data from the device to the Actigraph software then clear the device of your activity data.

Data Entry/Uploads

CGM: If you already use a Dexcom CGM your device data will be shared through your Dexcom Clarity account.

Food Diary: You will be asked to remember what you have eaten for the last 24-hours and enter it into the Automated Self-Administered 24-Hour (ASA24) Dietary Assessment Tool. This is a meal tracking diary run by the National Institute of Health (NIH).

These organizations may collect some information like your email address and health information. The organizations that own these have policies in place to protect your information. They use this information to provide the services of the apps and for internal purposes, like training and making the apps work better. For more information on their privacy policies, please visit their websites or ask the study team for copies.

Shipping Supplies

The study team may need to send supplies to you. If they do, they will use a study shipping account that belongs to JCHR. This means that JCHR may have access to your contact information through the shipper, like FedEx. Your shipping information will not be used for any other purpose.

Text or Email Messaging

The study team may use your contact information to call, text or email you during the study. They may contact you to send appointment reminders or to remind you to send the study supplies back. They are not allowed to send you private information by text or regular email because texting and regular email are not secure. This means that there is a risk that a message may be seen by someone that is not supposed to see it, like when an email gets hacked. Your email, phone number and your name will likely be in the text or email. If you think that the study team has texted or emailed information that they should not have, please contact JCHR at 813-975-8690 and ask to speak to the IRB Administrator. If you text or send a regular email to the study team, it is unsecure and what you put in the text or email is not protected.

CAN I STOP BEING IN THE STUDY?

You can stop being in the study at any time. If you decide to stop being in this study, you will not have any penalty or loss of any benefits that you normally get. You can get regular care like you normally would, but you will be asked to return any study supplies you may have.

Also, if at any time you don’t want to participate in or finish a test or procedure, then tell the study team. It is up to you. The study team will tell you if you can stay in the study without the tests or procedures, or if it means that your part in the study will be over. For example, if there is a question that you do not want to answer, then you may be fine to stay in the study. However, if you do not want to have your blood drawn, then you might not be able to finish the study.

If we find out that there is any important new information, you will be told about it. You will be able to decide if you want to continue in the study based on this new information.

The study may stop or the study doctor may decide to take you out of the study at any time too. You do not need to give permission for the study to stop or for the study doctor to remove you from the study. You will be told if this happens. Some reasons why you may be removed from the study include:

- The doctors feel that it is in your best interest
- You do not follow the study instructions

ARE THERE COSTS RELATED TO THE STUDY?

The study will pay for testing that is required solely for this study. You might have data fees for sending or receiving text messages. You may also have data fees if you use your phone or computer to do study tasks like questionnaires. Your study care center will have a laptop that you can use during your visit to do your questionnaires if you don't want to use your phone or computer. At the end of the study, or if you withdraw, you must return all study supplies to your study care center. You can either take them back to the study care center or the study team will provide you a pre-paid mailer. Any regular office visits or additional tests and procedures will be billed to you or your insurance company like they would be normally.

Please ask to speak to someone at your study care center if you want more information about what you or your insurance will be expected to pay.

IS THERE PAYMENT FROM THE STUDY?

If you take part in the study, you will receive up to $300 for your time. You may choose to not receive payment for participating. These payments will be made as follows:

Visit Procedures • Record Review • Vitals • Sample Collection • Questionnaire Completion	$75
Eye Imaging	$60
Insulin Diary	$20
ASA24	$30
Physical Activity Tracking	$15
Continuous Glucose Monitor (CGM)	$30
Optional: Pulse Wave Velocity and Pulse Wave Analysis	$20
Optional: 24-hour Blood Pressure	$50

Compensation for study participation will be made to you in the form of debit/gift card or check from your study care center throughout the study. You will not receive payment for activities that are part of your usual CF or CFRD care. For example, if the doctor changes your medication dosage during the same time as your study visit and wants to have a follow-up with you, the study would not pay you for going to this follow-up visit. You will receive payment for the optional procedures like pulse wave velocity and 24-hour blood pressure.

If you withdraw from the study, you will still be paid for the procedures that you have completed. You may be asked to repeat a procedure if the study team cannot use that information. If repeating the procedure requires you to schedule a doctor's visit outside of normal care, you will be reimbursed for your travel expenses.

If you would like reimbursement for your travel expenses, then please tell the study team. Direct and reasonable travel expenses for study required visits will be reimbursed. Direct and reasonable travel expenses are the actual cost of the most sensible travel option to get you to and from required study visits. You will be asked to provide receipts or proof of mileage. If you live more than 200 miles away from the study care center and will require a hotel and/or flight for your study visit, please tell the study team as soon as possible. The study team must get approval from the sponsor before they can reimburse these costs. The study team at your study care center or at the Jaeb Center for Health Research may be able to book some of your travel for you so you would not need to pay anything. Please talk with your study team about it while scheduling your visit.

Because payments made to you for participating in this study may be reportable to the Internal Revenue Service (IRS) as income, you may need to provide a Tax Form

W-9 to your study care center. These will not be shared outside of your study care center, other than as required by the IRS.

When thinking about being in a study, there are some money-related issues to consider as a part of making your choice. For example:

- If you get certain benefits from the government, like food assistance, then getting paid by the study might affect your ability to keep getting these benefits. You may need to talk to your benefits representative.
- If you are a non-US citizen, but you are participating within the US, then the IRS may require a withholding. You may need to talk to a tax consultant.
- If you have a US Visa, then your status may have earning limits. You may need to speak to an immigration attorney.

Please note that you can choose not to get paid. You will need to tell the study team or study doctor if you do not want to get paid. You do not need to tell them why. No one can make you choose not to receive compensation. It is up to you.

The use of your samples may result in commercial profit. The profits will not be shared with you.

WHAT HAPPENS IF I HAVE AN ILLNESS OR INJURY FROM THE STUDY?

This study does not have any more risk than you would have if you were not in the study. It is not expected that there would be any study related illness or injury. If you have an illness or injury that is related to your participation in the study, then you can get care like you normally would.

Signing this form and agreeing to be in this study does not mean that you lose any of your legal rights or release anyone involved in the research from their responsibilities.

CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS

If you have questions about this study or a research illness or injury, or if you have concerns, suggestions or questions about the study, then contact your study team using the contact information on the first page of this form.

If you have questions, comments or suggestions about the research you can contact the Jaeb Center for Health Research Institutional Review Board (IRB) Office at 813-975-8690 or irb@jaeb.org. You can also contact the IRB if you want more information about your rights, injury reimbursement, or the future use of your information or samples.

HOW WILL MY INFORMATION BE PROTECTED AND KEPT CONFIDENTIAL?

This section tells you about the use and disclosure (or “sharing”) of your personal Protected Health Information (PHI). This is like the information that is usually found in your medical records that will be collected for the study. Only the health information about you that is needed for this study will be used or disclosed. This information will be kept confidential and private as required by law. The specific types of information that will be released and used for this study are:

- Hospital discharge summaries
- Medical history / treatments
- Laboratory / diagnostic tests
- Biological specimen(s) and/or slide(s)
- Diagnostic imaging reports
- Diabetes records
- Full addresses or zip code

You are being asked to give your permission for your PHI to be shared from your doctors, clinics, and hospitals to the researchers doing this study. This is called giving your Authorization. The PHI is needed to do the study, so you will have to give your Authorization in order to be in the study. If you do not want to give Authorization, then you will not be able to be in the study.

Your Authorization for PHI lasts 50 years from the date that you sign this form or until the end of the study, whichever comes first. You may cancel your Authorization at any time. You will need to contact your study care center in writing, or you may contact the JCHR IRB Office at 813-975-8690 or irb@jaeb.org. When you fully cancel your Authorization, you are no longer part of the study. No new PHI will be collected or shared for the study, except if there is a safety concern. If there is a safety concern, you may be asked for more information, or your entire medical record may need to be reviewed. The researchers will have all the information that was collected for the study up to the time that you canceled your Authorization or are no longer in the study. Any information that has been received will remain in the study database after you withdraw.

The researchers will use a code that may have your initials or date of birth to keep your study information (or “study results”) together at the Jaeb Center for Health Research in Tampa, Florida. Your Authorization for the use and sharing of the coded study results will never end. Also, the following people or companies involved in this study may see your study results with things like your date of birth, initials, and date of procedures:

- your treating healthcare providers and their staff
- associated healthcare institutions and hospitals where you receive care

- Jaeb Center for Health Research
- Advanced Research and Diagnostics Laboratory (Central Laboratory)
- University of Wisconsin (Retinal Image Reading Center)
- National Cancer Institute (ASA24)
- Actigraph (Physical Activity Tracker)
- Dexcom if you choose to share your CGM data through Dexcom Clarity
- FedEx will see your contact information only for the purpose of sending you supplies.
- JCHR may see your contact information only for the purpose of sending you supplies. JCHR may also see your contact information and birthdate if you have asked for the study team to book your travel.
- Cystic Fibrosis Foundation
- University of California (Geocoding)
- Laboratories for the study and for storing your samples for future research

Sometimes people not directly working on the study need to see your PHI. For example, the Food and Drug Administration (FDA), other federal agencies, and committees that monitor safety may look at your information in the study. In most cases, the information will be coded instead of having your PHI, but not always. For example, if you are in this study, then this form could be reviewed and it would have your name on it. Once PHI is shared, it may no longer be covered by the privacy laws. Only the people that need to see your information are allowed to see it.

You have the right to see your records too. During the study, you may not be able to see or get copies of everything. The study team will be able to tell you if you will need to wait to get some information. When the study is over, you have the right to see all of your study records.

CERTIFICATE OF CONFIDENTIALITY

The National Institute of Health has given us a Certificate of Confidentiality for this study. This adds special protection for study information that identifies you and allows us, in some cases, to refuse to give out information that could identify you without your consent. This could be done when the information is requested by a federal, state, or local court, or public agency. If you need medical help, we may still share your identifiable information. As described in this form or in other cases, we may share identifiable information. For example, if the government inspects us, they may see your identifiable information. Your study doctor and research team will follow local laws and will tell the local or state authorities:

- If certain diseases are present;
- If they suspect neglect, abandonment, or abuse of you; and

- If your study doctor or research team learn that you plan to harm yourself or someone else.

CLINICAL STUDY REPORTING

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. A copy of one of the study consent form templates will also have to be posted on a federal Web site.

OTHER CONSIDERATIONS

The information and samples collected in the study may be used in future studies without additional permission from you. This may include research done by other researchers. The information that may be shared will not contain any identifiable information that could be used to identify you. There may still be a chance that someone could identify you, but this is not likely. A copy of the information collected as part of the study will be made public in a dataset. This will be done after the study ends. This dataset will not contain any PHI. The study results will also be made public. These results will not have any PHI either. Study results without PHI may be shared in medical journals and at scientific meetings.

A limited dataset that contains some PHI may be provided to certain researchers.

This PHI will not include things like your name, full address, identifying pictures, or medical record numbers. Any researcher would need to sign an agreement to protect your PHI before getting this dataset as required by law.

Your research team will be able to provide clinically relevant procedure results once they become available.

You may also have communication with the study team by phone, text, or by video (like FaceTime or Skype). There is a chance that someone could see or hear the conversation like they could if you were speaking or texting with anyone. The video communications will not be recorded.

STUDY INFORMATION FOR FUTURE USE

Some of your identifiable study information may be stored or used for future research by Jaeb Center for Health Research, the Centralized Endocrine & Diabetes Data Repository – Cystic Fibrosis (CEDaR-CF), the CF Registry, other researchers, and industry collaborators. This information includes things like dates of procedures, optical coherence tomography (OCT) and color fundus scans and photographs of the retina, and other possibly identifying information. The types of research that may be done with this information includes studies on CF and/or related health issues, like

CFRD. If someone got this information, then they might be able to figure out that it is your information.

OCT takes detailed images of the eye that allows the doctor to look at all the structures. Color fundus allows the doctor to see a flat image of the back of the eye and detect diseases in the eye. These scans and photographs of the retina are only identifiable if they can be matched to a database that already includes pictures of your retina for identification purposes. They could be used for publications, other research, or to help design future studies, or for teaching materials. The types of research that may be conducted with this information include analyses to help researchers better understand the condition being studied or plan future studies.

This information will be shared with researchers outside of the Jaeb Center for Health Research. The researchers may include endocrinologists, pulmonologists, or other experts of CF or CFRD. Researchers may ask for data that have your PHI. They will need to sign an agreement to keep this information confidential. This information from this study may be stored and used indefinitely. You will not be told about the specific purposes of the future research. If there is a certain kind of research study that you would not normally want to do, you will not know if a future study is like that. Also, the results from the future studies will not be shared with you.

It is not expected that you will have any benefit from allowing this information to be used for these future research purposes. The information may help people in the future.

You do not have to allow the use of this information for future purposes if you don't want to. If you decide that you do not want to allow the future use of your study information, then you cannot be in the main study either. This is because the future use is an important part of the study for the researchers. Your regular care outside of the study will not be impacted. Also, if you change your mind in the future, we will not be able to remove the information or samples once shared.

If informed consent is being completed electronically: If you agree to be in the study, you will be asked to sign this form by entering your unique username and password. This is called eConsent. This form may be printed and completed on paper if you prefer. You will be able to save or print copies of this form. You can also ask for a paper copy at any time at no cost. By signing this form electronically, the Jaeb Center will have your consent information, like your name. This information will be kept separate from your study results. It will be kept confidential and private.

IF INFORMED CONSENT IS COMPLETED ON PAPER, PLEASE COMPLETE THE REMAINING PAGES

Optional Pulse Wave Velocity and Pulse Wave Analysis Sub Study

This study includes an optional Pulse Wave Velocity and Pulse Wave Analysis Sub-study. Note: Not all centers are participating.

_____ (sign initials) I ***do*** give my permission to participate in the Pulse Wave Velocity and Pulse Wave Analysis Sub Study (if my center is participating)

_____ (sign initials) I ***do not*** give my permission to participate in the Pulse Wave Velocity and Pulse Wave Analysis Sub Study

Optional 24-Hour Blood Pressure Sub Study

This study includes an optional 24-Hour Blood Pressure Sub-study. This will be done one time for this study and is estimated to take about one day. Note: Not all centers are participating.

_____ (sign initials) I ***do*** give my permission to participle in the 24-Hour Blood Pressure Sub Study (if my center is participating)

_____ (sign initials) I ***do not*** give my permission to participate in the 24-Hour Blood Pressure Sub Study

Optional Biobank Specimen Collection

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. This part is optional. You can be in the study even if you do not do this part. 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 (blood, urine and stool) for future research use. These samples will not be used to identify you.

_____ (sign initials) I ***do*** give my permission for specimen banking

_____ (sign initials) I ***do not*** give my permission for specimen banking

Information Collection for Geocoding

The study will use your address or part of your address (such as your zip code), to allow researchers to look at how where you live may be related to your health. For example, we may look at access to food, healthcare, or transportation in your area—these are called *Social Determinants of Health (SDoH)*. We use a process called *geocoding*, which turns an address into map coordinates (latitude and longitude). These coordinates help link your location to general area-level data (like your neighborhood, census tract, or county).

_____ (sign initials) I ***do*** give my permission for the collection of my **full address** for geocoding
_____ (sign initials) I ***do*** give my permission for the collection of my **zip code only** for geocoding

Adult Consent and Authorization

Complete this page when the participant is an Adult. If the participant is a Minor, check "N/A" here and skip this page – N/A ☐

Adult Participant's Full Name (printed): ______________________________

By signing below, I agree to take part in this study. My signature means that:

- the consent form was provided in a language that I understand, and I have read this informed consent form
- I have been given the chance to discuss the study, in a language that I understand, and to have my questions answered to my satisfaction
- I freely choose to participate and I can withdraw at any time
- I allow the future use of identifiable study information as described in this form
- I will receive a copy of this consent form
- I authorize the use and disclosure of protected health information. This information is collected as part of participation in this study. I cannot be in this study without this permission.

______________________________	______________
Participant Signature	Date of Signature

If the Informed Consent was presented orally to the participant, the participant is only required to sign the short form. Check "N/A" here and skip this section – N/A ☐

JCHR IRB
APPROVED
17/Sep/2025

Minor's Legally Authorized Representatives (LARs) Permission and Authorization

Complete this page when the participant is a Minor. If the participant is an Adult, check "N/A" here and skip this page - N/A ☐

Minor's Full Name
(printed):____

I, ________________________________ (print name of adult) attest that I am one of the following individuals authorized to provide consent for the child named above as I am one of the following LARs (checkbox):

- ☐ Natural or Adoptive Parent; or if not the parent, then
- ☐ Legal Custodian; or
- ☐ Legal Guardian

By signing below, I agree to allow the child to take part in this study. My signature means that:

- the consent form was provided in a language that I understand, and I have read this informed consent form
- I have been given the chance to discuss the study, in a language that I understand, and to have my questions answered to my satisfaction
- I allow the future use of the child's identifiable study information
- I freely choose to allow the child to participate, the child and I can withdraw at any time
- I will receive a copy of this consent form
- I authorize the use and disclosure of the child's protected health information. This information is collected as part of participation in this study. The child <u>cannot</u> be in this study if I do not provide this permission.

____ ____________
LAR Signature Date

If the Informed Consent was presented orally to the LAR, the LAR is only required to sign the short form. Check "N/A" here and skip this section – N/A ☐

Designated Person Obtaining Consent

I certify that to the best of my knowledge:

- The participant and/or LAR(s) are who they say they are
- That the study information and written materials were provided to the participant and/or LAR(s) in a language that they understand, and that they understand the nature, demands, risks, and benefits involved in the participation of this study

I attest that I will ensure that study records will show that the participant/LAR provided consent and that I have co-signed *before* any study procedures, including data collection.

____
Investigator or Designee’s Printed Name

____
Investigator or Designee’s Signature

____
Date

Witness

NOTE: An impartial witness is required to sign when the Informed Consent Form is presented orally to the participant, or when otherwise required by local institutional policy. If the Informed Consent Form was presented orally to the participant, the accompanying study short form must be signed by the participant and witness.

By signing this form, you are indicating that:

- The information in this informed consent and the short form, as well as any additional information conveyed by the research personnel obtaining consent, was presented to the participant and/or LAR(s) in a language understandable to them, including all written information
- The participant/LAR's questions were answered and the responses of the personnel obtaining consent were presented in a language understandable to them
- The participant/LAR(s) was/were asked in a language understandable to them if they understood the information, and they responded affirmatively.
- I have witnessed the consent process and signatures as described.

______________________	______________________	______________
Witness Printed Name	**Witness Signature**	**Date**

If the Informed Consent was not presented orally to the participant, or if a witness was not otherwise required by institutional policy, check "N/A" here and skip this section – N/A ☐