Consent and Authorization Form

Project Title: Immune Profiles in CF Fungal Infection

Consent

NCT Number: Pending

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part. Throughout this form, whenever we say "you" or "your" we are referring to the individual participant who will be completing the study procedures. For participants under the age of 18 years, a parent must sign the consent form.

Why is this study being done?

This study is being done to learn more about fungus infections in the lungs of patients with cystic fibrosis. We don't know a lot about fungus in people with CF, but are concerned that it may make lung function worse over time. Sometimes, fungus can cause a more allergy type illness (allergic bronchopulmonary aspergillosis, or ABPA) that needs to be treated with certain medications at certain times. We don't know much about ABPA or how people get it, and we think that people with CF who have fungus in their sputum may be at risk for developing this and may have some allergy type illness as well. This study is trying to help understand fungus better in patients with CF and hopefully lead to new ways of testing and treating fungus in patients with CF.

You are being asked to be in this research study because you have cystic fibrosis.

Other people in this study

Up to 35 people from your area will participate in the study.

What Happens if I join the study?

If you join the study, we will consent you prior to your clinic visit, talking about the risks and benefits of the study. If you consent to be a part of the study, we will see you at your CF clinic visit. You will then come to your normal CF clinic.

Before the visit and after you are consented:

Study Activities	Perform During Study
Informed consent	x
History and physical	x
BMI Measurement	x
Environmental Questionnaire	x
Spirometry	x
Sputum Collection	x
Blood Draw	x

Sputum Collection: If you are not asked to provide a sputum in clinic, we may mail you a specimen cup to collect sputum at home. It comes with instructions. We will have you do your home airway clearance treatment and try to cough up a sputum sample and spit it into the mailed specimen cup. We will then ask you to put this on ice bring it to the hospital.

Below is a what will be done at the visit:

Measure height and weight: They will measure your height and weight like other visits.

Limited Physical Exam: A study doctor or nurse will examine you, for example, listen to your lungs and heart and look in your nose and throat.

Pulmonary Function Tests (Spirometry): This is a test that measures your lung function like you do at every clinic visit. You will be asked to take a deep breath and then blow into a mouthpiece as hard as possible and for as long as possible.

Sputum Collection: If you are unable to get sputum at home, You may be asked to cough to bring up mucus (sputum) from your lungs and spit it into a cup. You may have a procedure called a sputum induction to help you cough up mucus (see below). If you can't do this procedure, we will have you produce sputum on your own and use that. Your sputum will be sent for culture (like in CF clinic) to see if any bacteria or fungus are growing. We will also send it to test for certain types of molecules that give us signs for certain types of inflammation in your lungs. With your special permission, we will save any remaining sputum to be potentially used for other studies (see below).

> **If a sputum Induction is done:** A sputum induction helps you cough up mucus by inhaling sterile saltwater through a nebulizer. We will ask you to cough up mucus, and spit the mucus into a cup. You will be given albuterol before inhaling the nebulized saltwater. You will do a breathing test before and after the sputum induction. The study staff will watch you after sputum induction to make sure your lung function is okay. They will ask you questions about how you feel and might have you do more breathing tests

Questionnaire Completion: You or your parent/caregiver will be asked to complete a questionnaire at the visit or at home. Each questionnaire takes several minutes to complete. The questionnaires will ask questions about your environment and where you live.

Blood draw for testing and banking: We will use a small needle to collect blood from a vein in your arm. We will be measuring different molecules that give us signs of certain types of inflammation going on in your body. We will also be testing to see if you are allergic to certain types of fungus and mold. With your special permission, we will save any remaining blood to be potentially used for other studies (see below).

What are the possible discomforts or risks?

There are some risks related to the procedures used in the study. Most procedures are not different from procedures at your routine CF clinic visits.

Spirometry (PFTs): There is a small risk of wheezing, shortness of breath or increased cough when performing spirometry. These symptoms usually resolve quickly without the need for treatment.

Sputum Induction: A sputum induction will be done if you are unable to cough up sputum on your own. The saltwater used in this procedure can cause a sore throat. The following things may happen from inhaling the saltwater: coughing, wheezing, shortness of breath. To reduce these risks you will receive albuterol before starting the sputum induction. You will be monitored closely for symptoms by one of our respiratory therapists. The procedure will be immediately stopped if symptoms of shortness of breath or persistent wheezing occur during the procedure. If this occurs you will be given albuterol, an inhaled medication to improve wheezing.

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.

Blood draw: The risk of collecting blood includes initial discomfort, bruising, or mild bleeding. Infection at the site is rare, but possible. Sometimes people may feel lightheaded after giving blood and may faint, but this is rather uncommon. You may have the option to use numbing cream (EMLA) on the skin to prevent discomfort when they draw your blood.

Confidentiality: Being in any research study has the risk of loss of privacy or confidentiality. There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed. Below tells you how your information will be protected.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about fungal infections in patients with CF. We are also trying to learn more about allergies to fungus in patients with CF. By doing so, we may learn more about how fungus and allergies to fungus play a role in patients with CF. This may change how we treat people with CF and gives more information on how to further treat fungus infections.

This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks.

Who is paying for this study?

This research is being sponsored by a grant from the Cystic Fibrosis Foundation and the Colorado Translational Research Center (CTRC).

Will I be paid for being in the study?

You will be paid $50.00 for the study visit. It is important to know that payments for participation in a study are taxable income. This study provides payment for participation. Children's Hospital Colorado pays you using a debit card payment system. The cash value will be loaded onto a debit card when you finish certain study procedures. The Internal Revenue Service (IRS) requires that we report as income when we pay you. A research team member will ask you to provide your social security number or tax identification number to meet these IRS requirements. Without this number, we can't pay you for being in this study.

Do I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them. Additionally, if your pulmonary function testing is decreased by 20% or greater, you may need to be hospitalized for a more severe pulmonary exacerbation. Your primary CF provider will be contacted in the above scenarios in order to determine your clinical care.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Dr. Spencer Poore immediately. His phone number is 720-777-6181. We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Spencer Poore. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Spencer Poore at 720-777-6181. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Spencer Poore at 720-777-6181 with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055. You can also talk to a Subject Advocate at the Clinical Translation Research Center (CTRC). The phone number there is 720-848-6662.

Optional Consent for Data and Specimen Banking for Future Research

Dr. Spencer Poore would like to keep some of the data and tissue that is taken during the study but is not used for other tests. If you agree, the data and samples will be kept and may be used in future research to learn more about cystic fibrosis. The research that is done with your data and samples is not designed to specifically help you. It might help people who have cystic fibrosis and other diseases in the future. Reports about research done with your data and samples will not be given to you or your doctor. These reports will not be put in your health records. The research using your data and samples will not affect your care.

The choice to let Dr. Spencer Poore keep the data and samples for future research is up to you. No matter what you decide to do, it will not affect the care that you will receive as part of the study. If you decide now that your data and samples can be kept for research, you can change your mind at any

time and contact your study doctor to let him or her know that you do not want Dr. Spencer Poore to use your data and samples any longer, and they will no longer be used for research. Otherwise, they may be kept until they are used up, or Dr. Spencer Poore decides to destroy them.

When your data and samples are given to other researchers in the future, Dr. Spencer Poore will not give them your name, address, phone number or any other information that will let the researchers know who you are. Your data and samples will only be used for research and will not be sold. The research done with your data and samples may help to develop new products in the future, but there is no plan for you to be paid. The possible benefits of research from your data and samples include learning more about what causes cystic fibrosis and other diseases, how to prevent them and how to treat them. The greatest risk to you is the release of your private information. Dr. Spencer Poore will protect your records so that your name, address and phone number will be kept private. The chance that this information will be given to someone else is very small. There will be no cost to you for any data or sample collection and storage by Dr. Spencer Poore.

Please read each sentence below and think about your choice. After reading each sentence, circle "yes" or "no." If you have questions, please talk to your doctor or nurse. Remember, no matter what you decide to do about the storage and future use of your data and samples, you may still take part in the study.

I give my permission for my data and tissue to be stored in a central tissue bank at the CTRC Pediatric Core Lab for future use by the study investigators:

1. I give my permissions for my data and tissue samples to be kept by Dr. Spencer Poore for use in future research to learn more about how to prevent, detect, or treat cystic fibrosis.
   Yes No _____Initials
2. I give my permissions for my data and tissue samples to be used for research about other health problems (for example: causes of heart disease, osteoporosis, and diabetes).
   Yes No _____Initials
3. I give my permission for my study doctor (or someone he or she chooses) to contact me in the future to ask me to take part in more research.
   Yes No _____Initials

Who will see my research information?

The University of Colorado Denver (UCD) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- Children's Hospital Colorado (CHCO), CTRC Core Lab at CHCO
- University of Colorado Denver
- Other: Barbara Davis Center

CHCO shares a medical record system with the Barbara Davis Center and PedsConnect; therefore, it is also possible that your information could be viewed by healthcare professionals at these organizations.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. T. Spencer Poore
13123 East 16th Ave, Box 395
Aurora CO 80045 720-777-6181

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- The Cystic Fibrosis Foundation, who is the company paying for this research study.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private. You have the right to request access to your personal health information from the Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed.

Information about you that will be seen collected, used and disclosed in this study:

 Name and Demographic Information (age, sex, ethnicity, address, phone number, social security number, etc.). Your social security number will be collected for IRS monetary purposes and compensation, not for research.

 Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results

 Research Visit and Research Test records

What happens to Data, and Specimens that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data and specimens collected from you during this study are important to this study and to future research. If you join this study:

The data and specimens given by you to the investigators for this research no longer belong to you. Both the investigators and any sponsor of this research may study your data, and the specimens collected from you. If data, and specimens are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval. Any product or idea created by the researchers working on this study will not belong to you. There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

HIPAA Authorization for Optional Additional Study Procedures

In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above. If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____ I do not give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature (parent of children or subject age 18 years or older)

_____ Date:_____

Print Name:_____

Child Signature (Age 13-17)*: _____ Date:_____

Print Name: _____

*In addition to parent's signature

Witness Signature: _____ Date:_____

Print Name:_____

Witness of Signature ☐
Witness of consent process ☐

Consent form explained by:_____

Signature: _____ Date:_____

Print Name: _____