UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

University of Florida
Health Center
Institutional Review Board
APPROVED FOR USE
From 7/5/2012 Through 5/1/2013

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

If you are a parent, as you read the information in this Consent Form, you should put yourself in your child's place to decide whether or not to allow your child to take part in this study. Therefore, for the rest of the form, the word "you" refers to your child.

If you are a child or adolescent reading this form, the word "you" refers to you.

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Lung Microbiota and Inflammatory Response in Cystic Fibrosis (CF)

3. Who do you call if you have questions about this research study?

Principal Investigator: Gary Wang, MD (352) 392-3261

Other research staff: Dawn Baker, ARNP (352) 273-8380

4. Who is paying for this research study?

The sponsor of this study is University of Florida Department of Medicine.

5. Why is this research study being done?

The purpose of this research study is to evaluate microbiomes in your upper and lower respiratory tract. Microbiomes are different bacteria that can be identified using advanced technologies that identify the genetic components of the bacteria. Traditionally, different bacteria are identified in the airways by culturing the specimen obtained on a growth material. Microbiome technologies can detect bacteria that cannot be cultured using the traditional methods in the laboratory. Therefore, it can provide us with more comprehensive knowledge of the different bacteria that colonize the airways. Moreover, it can also provide us with information regarding the relative abundance of different types of bacteria in the airways.

You are being asked to be in this research study because you have CF or are a patient of the pediatric pulmonary division and are undergoing bronchoscopy as determined by your doctor.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

As part of your normal clinical care, your physician has determined that you will need to have a bronchoscopy to look at your airways. The airways carry air from your nose and mouth to your lungs.

During the procedure, your doctor passes a thin, flexible tube called a bronchoscope through your nose (or sometimes your mouth), down your throat, and into your airways.

The bronchoscope has a light and small camera that allow your doctor to see your windpipe and airways and take pictures. You'll be given medicine to make you relaxed and sleepy during the procedure.

Bronchoscopy usually is done to find the cause of a lung problem. Your doctor may perform a procedure called bronchoalveolar lavage while the bronchoscope is in your airways. In this procedure the doctor injects small amount of sterile salt water on your airways and suction it back through the scope where it is trapped and sent to the lab for culture and other tests. You will have already given consent for the bronchoscopy and the procedures related to it.

7. What will be done only because you are in this research study?

Before you have the bronchoscopy, you will be asked to give a throat swab. If you can cough up a sputum specimen we will ask you to do that rather than a throat swab. You may have had this done before in clinic and it involves sweeping a cotton swab to the back of the throat.

If a bronchoalverolar lavage is performed, then when the physician is collecting fluid to be sent off to the lab for tests, we are asking for one additional tube to be used for research purposes.

We are also asking to collect results from your medical records. This would include: results from any treatments of infections including hospitalizations, antibiotics treatment, or lab data including genetic test results (if you are a CF patient). If you have had a chest x-ray or CT of the chest or tests of your breathing function we are also asking for this information as well. This information is being collected to compare to the results of the microbiome data we are collecting

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

8. How long will you be in this research study?

One to two weeks once you have had bronchoscopy performed.

9. How many people are expected to take part in this research study?

We are expecting to enroll 65 subjects locally in this project.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

The throat swab may cause a gag reflex which is mild and temporary.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

11a. What are the potential benefits to you for taking part in this research study?

If the lung microbiome data that we collect addresses our research question this could be helpful to your treating physicians.

11b. How could others possibly benefit from this study?

If we can predict earlier risks to lung health we could theoretically intervene sooner.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

You may choose not to participate in this study and it will not affect your care.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form . They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

We will collect data up to the time you withdraw your consent but will not collect data after the date of the written request.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

If the study is stopped prematurely you may be withdrawn

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

The Sponsor will pay for provide all medical services required as part of your participation in this study as described above in the question "*What Will Be Done Only Because You Are In This Research Study*".

If you receive a bill for these services, please contact the principal investigator Gary Wang, MD, at 352-392-3261 or the study coordinator Dawn Baker, ARNP, at 352-273-8380.

All other medical services you receive would have been provided to you even if you were not in the study. These services will be billed to you or your insurance company. You will be responsible for paying any deductible, co-insurance, and/or co-payments for these services, and any non-covered or out-of-network services.

Some insurance companies may not cover costs associated with studies. Please contact your insurance company for additional information.

15. Will you be paid for taking part in this study?

You will be paid $25.00 for the throat swab.

16. What if you are injured because of the study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact principal investigator Gary Wang, MD, at 352-392-3261 or the study coordinator Dawn Baker, ARNP, at 352-273-8380 if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

Results of the bronchoscopy, genetic tests, throat culture tests. If you have had infant pulmonary function tests or a CT of the chest we will collect this data. As well as results of antibiotic treatment, and hospitalizations.

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

Results will be shared within research team to determine correlation of micriobiome data with your health status and with markers of airway and lung disease.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- the study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- the University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- United States and foreign governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections .
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others for 7 years

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use

and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

SIGNATURES

As a representative of this study, I have explained to the participant or the participant's legally authorized representative the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how privacy will be protected.

Signature of Person Obtaining Consent _____ Date _____

Consenting Adults

You (and/or the participant) have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your (or the participant's) privacy will be protected. You have received a copy of this Informed Consent Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

Adult Consenting for Self. By signing this form, you voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

Signature of Adult Consenting for Self _____ Date _____

Parent/Adult Legally Representing the Subject. By signing this form, you voluntarily give your permission for the person named below to participate in this study. You are not waiving any legal rights for yourself or the person you are legally representing. After your signature, please print your name and your relationship to the subject.

Consent Signature of Parent 1 / Legal Representative _____ Date _____

Print: Name of Legal Representative of and Relationship to Participant: ^ _____

Participants Who Cannot Consent But Can Read and/or Understand about the Study

Although legally you cannot "consent" to be in this study, we need to know if you want to take part. If you decide to take part in this study, and your parent or the person legally responsible for you gives permission, you both need to sign. Your signing below means that you agree to take part (assent). The signature of your parent/legal representative above means he or she gives permission (consent) for you to take part.

Assent Signature of Participant _____ Date _____

CONSENT TO COLLECT AND STORE TISSUE FOR FUTURE RESEARCH WHEN IDENTITY OF SUBJECT IS CODED AND THE CODES ARE KEPT IN LOCKED FILES BY THE PERSON CONDUCTING THE RESEARCH

As part of the research project Dr. Gary Wang M.D., Ph.D. would like to store some of your BAL/Throat/Serum that is not needed for your medical treatment or that was not needed for the research study. If you agree, Dr. Gary Wang will keep the samples in a specimen bank so that they may be used in future research to learn more about microbiota and other medical problems. Researchers are trying to learn more microbiota and how it impacts our health. Even if the research that is done on your samples cannot be used to help you, it might help other people with medical problems.

Many medical problems may arise due to the environment or from genetic factors. Your microbiota or general health may come from one or both of these causes. Genetic factors are those that people are born with and that can affect other family members. There may be genetic testing done in the future that would provide information about traits that were passed on to you from your parents or from you to your children. A new 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 based on your genetic information. This law protects you in the following ways: (1) Health insurance companies and group health plans may not ask for your genetic information obtained during this research study; (2) Health insurance companies and group health plans may not use your genetic information when making decisions about your eligibility for insurance or your premiums; (3) Employers with 15 or more employees may not use your genetic information obtained during this research study when making a decision to hire, promote, or fire you, or when setting the terms of your employment. Be aware that GINA does NOT protect you against discrimination by companies that sell life, disability, or long-term care insurance. If you think that these laws have been violated, it will be up to you to pursue any compensation from the offending insurance company and/or employer.

Dr. Gary Wang or *his* successor, will be responsible for making sure that your samples are protected in the specimen bank and that your medical information is kept confidential. Your samples will not be stored with your name or other identifying information but instead will be given a code number to protect your identity. The samples and this code number will only be given to researchers whose research is approved by the Institutional Review Board (IRB). (An IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). The researchers will not be told who you are. Because the nature and value of any future research cannot be known at this time, any results obtained from using your tissue will not be given to you or your doctor.

The people who use your samples to do research may need to know more about your health. If researchers ask for reports about your health (information from your medical records), Dr. Gary Wang will not give them or anyone else your name, address, or

phone number (unless you are willing to be contacted in the future to take part in more research). Although every effort will be made to keep your information confidential, there is a small risk that an unauthorized person may review your information. Therefore, there is a very slight risk that a test result could be linked to your identity and inadvertently disclosed to you or to a third party. If you were to receive the result of a genetic test that indicated a problem, it could cause anxiety or other psychological distress. In addition, you might have to decide whether or not to discuss the findings with members of your family. If a third party learned the results, there is a risk of discrimination that could result in stigma and of the unpredicted disclosure of this information to others. You can discuss these issues further with your doctor or nurse and you can request a consultation with a genetic counselor if you wish to discuss these possible risks. In addition, there are laws that require that research records that have your name on them may be shown to people who make sure that the research is being done correctly. As mentioned in the accompanying consent form, the University of Florida Department of Medicine, and the Institutional Review Board have the legal right to review and copy your medical records related to this research.

There will be no cost to you for any specimens collected and stored in the specimen storage bank. Your samples will be used only for research and will not be sold. Some new products might be made because of the results of the research that uses your samples. These products might be sold sometime in the future, but, should this occur, you will not get paid.

The choice to let Dr. Gary Wang keep your samples for doing research is entirely up to you. No matter what you decide to do, it will not affect your care. If you decide that your tissue can be kept for research but you later change your mind, tell Dr. Gary Wang who will remove and destroy any of your samples that he still has. Otherwise, the samples may be kept until they are used up, or until Dr. Gary Wang decides to destroy them.

Please review statements 1, 2, 3, and 4 and then circle the answer that is right for you. If you have questions, please talk to your doctor or nurse.

1. I agree that my samples may be stored, coded to protect my identity, and that my identity will not be disclosed to anyone without my permission, except when required by law.

   YES NO Initials_____

2. I agree that some excess samples may be kept by Dr. Gary Wang for use in future research to learn more about microbiota.

   YES NO Initials_____

3. I agree that my samples may be used for research to answer other medical questions that are not necessarily related to microbiota

   YES NO Initials_____

4. I agree that my doctor (or someone he/she chooses) can contact me in the future to ask me to take part in more research.

   YES NO Initials_____