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 8/1/2012 Through 7/31/2013

INTRODUCTION

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

Name of person seeking your consent:_____

Place of employment & position: _____

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?

Early MRSA therapy in CF – culture based vs. observant therapy (treat or observe) (**STAR-too** – **ST**aph **A**ureus **R**esistance – **t**reat **o**r **o**bserve) STAR-too-10K0

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

Principal Investigator: Pamela Schuler, MD

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

4. Who is paying for this research study?

Dr. Marianne Muhlebach (University of North Carolina at Chapel Hill) and Dr. Christopher Goss (University of Washington) are the investigator-sponsors for this study.

Cystic Fibrosis Foundation Therapeutics, Inc. is paying the CF research team at the University of Florida to conduct the study.

5. Why is this research study being done?

People with CF often have thick mucus in the airways of the lungs that is hard to cough up. The mucus can build up and eventually lead to chronic cough and infections. Bacteria often cause these lung infections. Methicillin-resistant *Staphylococcus aureus* (MRSA) is a bacteria found in the lungs of some people with CF; these bacteria are also found in people without CF. MRSA is more resistant to antibiotics than other forms of the *Staphylococcus aureus.* In both people with CF and people without CF, MRSA can sometimes make people sick and other times people can have the bacteria without getting sick. It is not known how often MRSA makes people with CF sick and if we need to get rid of it. CF doctors do not know the best way to treat the bacteria either.

The purpose of this research study is to try to answer the following questions:

- How often does MRSA go away without treatment?
- If antibiotics taken by mouth and special cleaning methods are used, will respiratory cultures be negative for MRSA? If so, for how long will the cultures be negative?
- Will the people who had the treatment feel better and need fewer antibiotics than the people who did not have the treatment during the study?
- Does the treatment have side-effects or take so much time that people would not want to do it?

People with CF who agree to take part in this study must have a recent respiratory culture that was positive for MRSA. Several tests and procedures would be completed at the first study visit to see if it is safe to be treated with the study medicines. A computer will then assign each person by chance to one of two groups. One group will receive the study treatment and the other group will be observed. This is called randomization. The CF research team members and the participant will know to which group he or she has been assigned.

You are being asked to be in this research study because you have cystic fibrosis and have had a recent culture from your throat or sputum that has grown MRSA.

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)?

You would receive normal CF clinical care. You will not be treated for MRSA unless you have symptoms of a respiratory infection and this treatment will be decided by your regular CF doctor.

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

Study Visits and Procedures

If you agree to take part in the study, you will come to the clinical research center for a total of six study visits. The study visits are listed in the chart below.

The study compares two groups and you will be assigned by chance (randomized) to one of the two groups. One group, the **Treatment group,** will be treated for 2-3 weeks. The other group, the **Observed group,** will be prescribed antibiotics if there is an increase in symptoms of lung disease. During the first four weeks of this study, the symptoms have to be typical of a CF exacerbation and your doctor would decide how to treat you. After the first 4 weeks all people in the study can be treated as is necessary.

Some tests and procedures will be done at the visits to help the researchers learn about the safety of the study treatments. The results will also help the researchers to learn if a treatment is helping or not. The tests that would be done include:

- **Blood Collection:** Blood will be collected to check your kidney and liver function at the first study visit. A small needle will be used to collect blood from a vein in your arm. About 1 -2 teaspoons of blood would be collected. If you would like, your skin can be numbed with some medicine before the needle is used. This may help you not feel the needle prick as much. If you are 12 years or older, blood will be collected at the end of treatment (Visit 2). Blood will be collected at Visit 3 if the results from Visit 2 are not normal or you missed Visit 3 blood collection.

- **Pregnancy Test:** Some of the study drug(s) can harm an unborn baby. Because of this, you should not become pregnant if you join this study. All females who have menses and can potentially become pregnant will have a pregnancy test at Visit 1. At Visit 2 only those in the treatment group will have a pregnancy test. If you join the study and have a positive pregnancy test, we would tell you about the test results.

- **Spirometry (PFTs)**: If you are 6 years old or older, you will be asked to take a test that measures your lung function. 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. This is the same test which is done when you come to CF clinic.

- **Study Cultures**: Samples for the study will be collected and sent to the laboratory at the University of North Carolina for testing. If MRSA is isolated from your specimens additional tests of the bacterial DNA will be performed to help us understand more about MRSA in people with CF.

- *Sputum cultures*: If you are able to, you will be asked to cough up mucus into a cup, which will be collected for testing.
- *Swabs*: A cotton swab will be inserted briefly into the back of your throat. We would use a second swab to rub the insides of both nostrils (nose). A third swab will be rubbed on the skin in your armpit and your groin, the area between your leg and lower abdomen, to collect bacteria from your skin for testing.
- We will also contact the laboratory here at our hospital to see if the MRSA isolate from your last clinic visit is available and if so we will sent to the laboratory at North Carolina for some additional tests.

- **Treatment Log:** You will be given a treatment log if you are randomized to the treatment group. This is a small booklet where you will write down when you complete the study treatments. We would ask you to do this every day. If you are in the observed group, you would not need to complete this treatment log.

Research Study Visits:

If you take part in all the study visits, you would be in the study for approximately 6 months.

Visit #	Purpose and Procedures	How much time the visit will take
Visit 1 "	The following tests and procedures will be completed at this visit. The results will allow the CF research team to decide if you meet the requirements to be in the study. • Review the study and consent with the CF research team and sign the consent and HIPAA forms • Review your current health and medications • Complete some questionnaires about your health and quality of life • Have a physical exam by a CF doctor • Have blood collected (approximately 2 teaspoons) • Have blood collected (approximately 1 tsp) for a pregnancy test if you are a female, have started menstruation and able to become pregnant • Complete a spirometry test if you are 6 years or older • Cough sputum into a cup if you are able • Have cultures collected from your throat, nose, armpit and groin using cotton tipped swabs • Show you can gargle water if you are 10 years old or younger	About 3 hours

Visit 1a (Day 0) (Approx. 5-14 days after Visit 1)	**This visit will be scheduled only if you are assigned to the treatment group** • Receive your treatment kit and gloves from the CF research team • Learn about taking the study medications, cleaning instructions and completion of the Treatment Log • Review contact information for questions, side effects, changes in health, and emergencies	About 1 hour
Phone call (Day 7 ±2)	• Discuss any changes to your health or medications with the research team	10 - 30 min
Visits 2 (Day 15 +2)	The tests and procedures completed at this visit will help the researchers collect information about your health during the study. • Complete questionnaires about your health and quality of life • Discuss any changes to your health or medications with the research team • Have a physical exam by a CF doctor • Complete a spirometry test if you are 6 years or older • If you are in the treatment group: a. Review your Treatment Log entries b. Collect your unused study medications and treatment supplies and used bottles of medication. c. Have blood collected (approximately 2 teaspoons) if you are 12 years or older and in the treatment group, d. Have blood collected (approximately 1 teaspoon) for a pregnancy test if you are female, have menses and able to become pregnant e. Review cleaning during the next week of the treatment program	About 2 hours

Visit #	Purpose and Procedures	How much time the visit will take
Visit 3 (Day 28 ± 2) **Visit 4** (Month 3), **Visit 5** (Month 6)	These visits will be combined with your CF clinic visit whenever possible. If some of the tests or procedures are done during clinic, the results may also be used for the study. The tests and procedures completed at this visit will help the researchers collect information about your health during the study. • Complete questionnaires about your health and quality of life • Discuss any changes to your health or medications with the research study team • Have a limited physical exam by a CF doctor or research nurse • Complete a spirometry test if you are 6 years or older • Cough sputum into a cup if you are able • Have cultures collected from your throat, nose, armpit and groin using cotton tipped swabs • ***At Visit 3 only: if you are in the treatment group:*** a. Review your Treatment Log entries b. Collect your unused study medications and treatment supplies and used bottles of medication. c. If your blood test results were abnormal at Visit 2, have blood collected (approximately 2 teaspoons)	About 2 hours

Study Treatments (Treatment Group Only)

If you are randomized to the treatment group, you will be asked to participate in the MRSA study treatment program. This study treatment program will be done in addition to your normal CF care. If you have problems with taking any study medicine or doing the cleaning methods, the CF Research Nurse or Coordinator will be able to help with suggestions and support.

The study treatment program is described below:

Study Treatment Medication	How often and how long	Instructions
Mupirocin Nasal ointment	Twice a day for 5 days	Use a cotton tipped swab to apply to the skin around each nostril
Rifampin	Twice a day for 14 days	Take this medicine by mouth; may be capsules or liquid

Trimethoprim/Sulfamethoxazole (TMP/SMX) (also known as Bactrim or Septra) ***OR*** Minocycline (only if you are at least 8 years old and are allergic to TMP/SMX or do not tolerate TMP/SMX)	Twice a day for 14 days	Take this medicine by mouth; may be tablets, capsules or liquid

Cleaning Methods	How often and how long	Instructions
0.12% Chlorhexidine mouth rinse	Twice a day for 14 days	Use a special mouth wash to swish but not swallow
Body wash including 2% Chlorhexidine body cloth	Once a day for 5 days	Thorough bathing followed by rubbing your skin with a medicated cloth
Surface cleaning wipes	Once a day for 3 weeks	Using Gloves wipe off the surface of faucets, doorknobs, keyboards and other areas that you frequently touch. Note the surface cleaning wipes must not be used to on the skin. Keep out of the reach of children
Laundering of towels and bed linens	Once a week for 3 weeks	Use hot water to wash all towels, wash cloths and bed linens

Observed Group

If you are randomized to the **observed group**, you will continue your normal CF care. You will not be treated for MRSA unless you have symptoms of a respiratory infection. Your treatment would be decided by your regular CF doctor.

Both Groups

For participants in both the treatment and observed groups, the research team will need to know if you have a respiratory illness or receive antibiotics during the 6-month study. If you get sick between study visits and go to a doctor, you will be asked to call the CF research coordinator, Dawn Baker at (352) 273-8380.

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?

Approximately 6 months.

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

90 people are expected to participate across 10-15 centers in the United States. We anticipate enrolling 5 people locally.

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?

Antibiotic Medications: The medications included in this study treatment program are antibiotics which have been approved by the U.S. Food and Drug Administration (FDA). These medications have been used to treat CF and non-CF patients for many years.

Generally, these antibiotics are all well tolerated. However, they can sometimes cause an upset stomach or diarrhea. If this happens and does not stop after one day or becomes more intense or you have severe nausea, vomiting or diarrhea; you must contact the CF research doctor or nurse right away.

Two of the medications, TMP/SMX and minocycline, can increase sensitivity of your skin to the sun and cause severe sunburn. It is best to avoid the sun, sunlamps, or tanning while taking these medications. You must wear clothing to cover your skin and use high factors of sun screen lotion if you are in the sun.

Other possible side effects by individual antibiotic are described in the chart below.

Rifampin	The most common side effects of rifampin are: • Reddish coloration of the urine, sweat, sputum, and tears; soft contact lenses may become permanently stained • The reliability of hormonal contraceptives (birth control pills, "patch" etc.) may be effected The following side effects occur infrequently. You should call your CF research nurse or doctor right away if you have any of these side effects: • Yellowing of the eyes or skin • Fever • Numbness, pain or tingling in the arms or legs • Unsteadiness or weakness • Blurred vision or eye pain • Bloody or dark urine • Unusual bleeding or bruising • Severe nausea or vomiting
Trimethoprim /sulfamethoxazole (TMP/SMX)	The most common side effects of TMP/SMX are • abdominal pain • stomach upset or nausea • allergic skin rash (occurs in 1- 4 out of 100 patients) The following side effects occur infrequently. You should call your CF research nurse or doctor right away if you have any of these side effects: • swelling in your face or hands • swelling, tingling or blistering in your mouth or throat • chest tightness • trouble breathing • any blistering or peeling of skin • red skin rash • fever • sore throat • pale skin • body aches • dark-colored or pale stools • confusion

Minocycline (will only be prescribed if you are allergic or do not tolerate TMP/SMX and are at least 8 years old)	The following side effects of minocycline occur infrequently. You must call your CF research nurse or doctor or the emergency study contact right away if you have any of these side effects: • itching or hives, • swelling in your face or hands, • swelling or tingling in the mouth or throat • chest tightness, • trouble breathing,

	• blistering, peeling or red skin rash, • a change in how often you urinate, • fever, • dark colored urine or pale stools, • headache • blurry vision . Minocycline is in the class of drugs known as tetracyclines. Tetracyclines have been shown to cause birth defects. If you are female and of childbearing age, you must abstain from sexual activity or use birth control while taking this medication.
Mupirocin Nasal Ointment	Side effects of Mupirocin nasal ointment occurring in less than 5 of 100 people include: • burning/stinging of the nose • stuffy nose • headache, • bad taste in the mouth • sore throat

Other Treatments/Cleaning

0.12% Chlorhexidine mouth rinse	In people who have used chlorhexidine oral rinse ***for 6 months (for this study you would be asked to use the rinse for 2 weeks)***, the following side effects have been reported: • change in taste • mouth irritation • increase in tartar on teeth • staining of teeth, mouth, tooth fillings, dentures, other mouth appliances, which is similar to that seen with coffee or tea. Most stains are temporary and go away on their own or can be removed by a dental cleaning.
2% Chlorhexidine body cloth	A possible side effect of the 2% chlorhexidine is skin irritation. In rare cases, an rash on the skin may occur if you are allergic to chlorhexidine.
Surface cleaning wipes	Skin irritation can occur from contact with the wipes. Gloves should be worn to protect your skin when using the wipes.

Other possible risks to you may include:

Study Procedures

There are some minimal risks related to the procedures used in the study. These procedures are not different from procedures you have performed at some of your routine clinic visits:

Blood collection:	The risk of collecting blood includes soreness, bruising, mild pain, mild bleeding or infection at the site. Some people feel faint or light-headed.
Skin numbing medicine:	Medicine may be used to numb your skin to reduce the pain from the blood collection needle used for the blood collection. This medicine may cause the area of your skin where it is applied to look pale or red and may cause some swelling. These reactions are mild and will resolve within 1 to 2 hours.
Spirometry:	There is a small risk of wheezing and shortness of breath. If you have recently had an air leak from the lungs (pneumothorax) or you are coughing up blood, you should tell your research doctor or nurse to help them to decide if you should do spirometry.
Throat swab	The collection of the throat swab may cause minor brief discomfort, gagging or coughing
Nose swab	The collection of the nose swab may cause minor brief tickling or discomfort.
Armpit/groin swab	There are no risks from swabbing the skin at these sites.
Sputum collection	Coughing up sputum may cause brief coughing or shortness of breath.

Pregnancy

You may not participate in this study if you are pregnant or currently breast feeding. If you are pregnant or become pregnant, or if you are breast-feeding while taking part in the study treatment program, you or your unborn child may be exposed to an unknown risk.

If you are female and able to become pregnant, you agree to have a pregnancy test done before beginning and at the end of the study treatment. You must also agree to avoid sexual intercourse or use a birth control method judged to be effective by your research doctor. As noted above, rifampin can affect the reliability of the birth control pill or "patch", therefore a barrier method (such as condoms) must also to be used. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the research nurse or doctor as soon as possible of any failure to use your birth control method, or if you become pregnant. Either may result in your being withdrawn from the study.

A Data Safety Monitoring Board will review the information from this research study. This board is made of a group of experts. They are responsible for looking at how people in the research study are doing.

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?

We do not know if you will benefit if you take part in this study. Half of the people in the study (treatment group) will receive the study antibiotics and use the study cleaning supplies and procedures. Half of the people (observed group) will receive no study treatment unless they have lung symptoms. It is not know which method will work better for people with CF who have new MRSA respiratory cultures.

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

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

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?

Taking part in research is voluntary. You do not have to be in this research study in order to receive treatment. If you decide not to take part in this research, your CF doctor may prescribe standard treatment for MRSA, which may include the study medications. Your CF doctor may also have recommendations about cleaning and skin treatment for people with cultures that are positive for MRSA.

Please talk to your doctor or the CF research team about these options. Typically at the University of Florida, MRSA is not treated unless there are symptoms.

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?

Once you withdraw from this study, no further information will be collected.

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

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

1) You do not follow study requirements
2) The principal investigator feels that is in your best interest to 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 provide for all medical services and activities 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*".

Study antibiotics, 0.12% Chlorhexidine mouth rinse, 2% Chlorhexidine body cloths, and surface cleaning wipes (Sani-Cloths Plus) and gloves, will be provided at no cost to you while you are participating in this study, if you are in the treatment group only.

If you receive a bill for these services, please contact Dr. Pamela Schuler at 352-273-8380 or Dawn Baker, ARNP at 352-273-5417.

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?

All participants will receive up to $225.00 to cover expenses and time for participating in the study. For Visit 1, you would receive $75.00. For visits 2 and 3, you would receive $50.00 each. For Visits 4 and 5, you would receive $25.00 each. You will not be paid for any missed visits.

Participants will receive also reimbursement for parking and mileage at the current federal business mileage rate. Mileage will be determined using a internet mapping program. Payments will be made after each visit.

If you are paid for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. If the payments total $600 or more, the University must report the amount you received to the Internal Revenue Service (IRS). If you have questions about the collection and use of your Social Security Number, please visit:
http://privacy.ufl.edu/SSNPrivacy.html

Because CF is a rare disease, please note that if you are currently receiving SSI, Medicaid or Medicare low-income subsidies, you are now able to receive up to $2000 in a calendar year as payment for study participation without it affecting your continued eligibility for these benefits. Please ask your study coordinator for details.

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

If you are injured as a direct result of your participation in this study, the professional services that you receive from any University of Florida Health Science Center health care 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 **Dr Pamela Schuler at (352) 265-0111 and ask for the pediatric pulmonologist on call** 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:

Medical history and physical exam, vital signs, lung function testing, throat or sputum results and laboratory results as well as confirmation of CF diagnosis. As well we will ask that you complete several questionnaires and will review your medications and any pulmonary symptoms you may have.

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):

- To determine how often MRSA will go away without treatment, if antibiotics taken by mouth and special cleaning methods is effective in treating MRSA. Also we will look to see if people who were on the treatment arm did better and need fewer antibiotics than the people who did not have the treatment during the study? And lastly, does the treatment have side-effects or take so much time that people would not want to do it?

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:

- The study sponsor (listed in Question 4 of this form).
- Cystic Fibrosis Foundation Therapeutics Inc
- Therapeutics Development Network Coordinating Center and their representatives
- 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 and this authorization will not expire

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.

Consent For Collection and Use of CFF Registry ID Number (Optional)

INTRODUCTION

The Cystic Fibrosis Therapeutics Development Network (CFFT TDN) has created a secure data storage system for data from clinical research studies called the "Data Archive". The data from clinical studies in the Data Archive will be used for future research about CF. These studies may help us to understand CF better and to help us to take better care of people who have CF. The data may also be used to help design other research studies in CF.

In the past, you have given your permission for information about your clinical care to be included in the Cystic Fibrosis Foundation's (CFF) Patient Registry database, and a unique identification number was assigned to label your registry data.

You are being asked to give permission for the collection of your CFF Registry Identification (ID) Number during the "STAR-too" study. If you agree to allow your CFF Registry ID Number to be collected in this study, this unique number will be used to label your data. The identification number will let the CFFT TDN link your data from this research study with the data in the registry database. If you have given permission for your data from more than one study to be archived, the CFF Registry ID will also allow the CFFT TDN to link your clinical data across those studies.

WHAT HAPPENS TO ME IF I AGREE TO TAKE PART?

There are no additional tests or procedures that you have to do because we will be using your CFF Registry ID Number collected during the "STAR-too" study.

WHAT ARE THE RISKS OF PROVIDING MY CFF REGISTRY ID NUMBER?

There are no physical risks or discomforts from the storage of your CFF Registry ID Number. One of the risks of allowing us to keep the data is that information about you might be released accidentally. To minimize this risk, the list showing the link between the CFF Registry ID Number and your study data including initials and birth date is kept on a separate, secure computer server that is protected with passwords and can only be accessed by select individuals at the CFFT TDN.

ARE THERE BENEFITS PROVIDING MY CFF REGISTRY ID NUMBER?

The research that is done will probably not help you. It might help people who have CF in the future by providing researchers with the ability to address new research questions about CF.

WILL I BE PAID TO PROVIDING MY CFF REGISTRY ID NUMBER?

You will not be paid for the use of your CFF Registry ID Number. If any new therapies, products or procedures are developed from studying your health information, you will not receive any money.

WHAT ARE THE COSTS OF PROVIDING MY CFF REGISTRY ID NUMBER?

There is no cost to you or your insurance company for the storage or use of your CFF Registry ID Number.

WHAT ABOUT CONFIDENTIALITY?

Researchers using data from the Data Archive will not be able to identify you. If a researcher wants to use your data, the researcher must have approval from the Institutional Review Board (IRB) at their institution and the Cystic Fibrosis Foundation. Upon approval, the study data will be linked at the CFFT TDN and upon completion of the linkage, all identifying information in the study data will be removed for the remainder of the project.

Because we do not know what studies your data will be used in, you will be unable to learn about the studies in which the data was used. Results from research studies using data from the Data Archive may be published in medical journals or presented at scientific meetings, but your name will not be used.

WHAT IF I DON'T WANT TO PROVIDE MY CFF REGISTRY ID NUMBER?

The choice to let us store your CFF Registry ID Number from the study and link it to your data is up to you. No matter what you decide, it will not affect your regular care. You can still take part in the STAR-too study.

CAN I CHANGE MY MIND LATER?

Even if you decide now that your CFF Registry ID Number can be used for research, you can change your mind later. Changing your mind later will not affect your regular care.

If you change your mind about allowing us to collect your CFF Registry ID Number, please write to Dr Schuler and let her know. Dr Schuler will tell the people at CFFT TDN that you have changed your mind. The CFF Registry ID Number will be removed from the data for this study.

WHAT IF I HAVE QUESTIONS ABOUT THIS STUDY OR PROVIDING MY CFF REGISTRY ID NUMBER?

If you have questions about this research or about this study, please contact Dawn Baker, ARNP at (352) 273-5417

SUBJECT'S STATEMENT

Please read each of the choices below. Think about your choice. If you have any questions, please talk to your doctor or a nurse or a member of the research team. ***Initial*** *the line next to your choice.*

____ I AGREE to have MY CFF REGISTRY ID NUMBER COLLECTED and sent to the CFFT TDN DATA ARCHIVE.

____ I do NOT want to have MY CFF REGISTRY ID NUMBER sent to the CFFT TDN Data Archive.

Consent For Storing Bacterial (MRSA) Isolates and Leftover Serum (Optional)

INTRODUCTION

You are being asked to give permission for some of your specimens from the STAR-too study to be saved (banked) for future CF studies. We would like to save any bacterial (MRSA) isolates and any serum leftover from the blood draw performed for safety lab testing.

This form provides information that may help you decide whether to allow some of your bacterial (MRSA) isolates and any serum leftover from the blood draw performed for safety lab testing.

WHAT ARE SOME GENERAL THINGS THAT I SHOULD KNOW ABOUT A "SPECIMEN BANK"?

The bacterial (MRSA) isolates and any serum leftover from the blood draw performed for safety lab testing that would be saved and stored could be used for future research studies to learn more about CF. Future research studies in which your bacterial (MRSA) isolates or any serum leftover from the blood draw performed for safety lab testing may be used have not yet been determined. Understanding more about CF may help us in designing future CF research studies and may also help us to take better care of people who have CF.

WHAT HAPPENS TO ME IF I AGREE TO TAKE PART?

There are no additional tests or procedures that you have to do because we will be using specimens collected during the STAR-too study.

WHAT HAPPENS TO MY SPECIMENS?

As part of the study called "STAR-too" we will be collecting samples (sputum, swabs) from you. If you agree, we would like to save any MRSA bacteria that are isolated from these specimens. In addition, we will be collecting blood from you at Visit 1 to perform safety lab testing to confirm your eligibility for the study. We would like to save any leftover serum (after the safety lab testing is complete). The bacterial (MRSA) isolates and leftover serum will be stored at the University of North Carolina at Chapel Hill Microbiology Lab or another site. The specimens will be labeled with a number, not with your name. The bacterial (MRSA) isolates and leftover serum will be kept until they are used up or destroyed. The bacterial (MRSA) isolates and leftover serum will not be sold.

If a researcher wants to use the bacterial (MRSA) isolates or leftover serum, the researcher must have approval from an Institutional Review Board (IRB) before the University of North Carolina laboratory will send the researcher the specimens. For-profit companies may also ask to use the bacterial (MRSA) isolates or leftover serum and need the same approval before the specimens will be given to them.

Because we do not know what studies your bacterial (MRSA) isolates or leftover serum will be used in, you will be unable to learn about the studies in which the specimens were used. You will not get the results of any tests that were done on the specimens.

Results from research studies using your bacterial (MRSA) isolates or leftover serum may be published in medical journals or presented at scientific meetings, but your name will not be used.

WHAT ARE THE RISKS OF TAKING PART IN THIS STUDY?

There are no physical risks or discomforts from the storage of the bacterial (MRSA) isolates or leftover serum. One of the risks of allowing us to keep the bacterial (MRSA) isolates is that information about you might be released accidentally.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

The research that is done with your bacterial (MRSA) isolates will probably not help you. It might help people who have CF in the future.

WILL I BE PAID TO TAKE PART IN THE STUDY?

You will not be paid for the bacterial (MRSA) isolates or leftover serum. If any new therapies, products or procedures are developed from studying your specimens, you will not receive any money.

WHAT ARE THE COSTS OF TAKING PART IN THE STUDY?

There is no cost to you or your insurance company for the storage or use of your bacterial (MRSA) isolates or leftover serum.

WHAT ABOUT CONFIDENTIALITY?

We will label your bacterial (MRSA) isolates and leftover serum with a number, not your name. For the MRSA isolates: we will keep your date of birth, and other information that might identify you separate from your specimens. The CF TDN keeps a list that links the number on the specimen with some identifying information (such as initials and birth date). The list showing the link between the number and your initials and birth date is kept in a separate secure database that is protected with passwords. For the leftover serum: the number used to label the specimen will not be linked to any identifying information about you. No one looking at the bacterial (MRSA) isolates or leftover serum in the specimen bank can identify you.

Researchers that get bacterial (MRSA) isolates or leftover serum from the "Specimen Bank" will not be able to identify you. Your name will not be used in any published reports.

We will not put the results of the research in your medical record.

WHAT IF I DON'T WANT TO TAKE PART IN THE STUDY?

The choice to let us keep your bacterial (MRSA) isolates and/or leftover serum is up to you. No matter what you decide, it will not affect your regular care. You can still take part in the STAR-too study.

CAN I CHANGE MY MIND LATER?

Even if you decide now that your specimens can be used for research, you can change your mind later. Changing your mind later will not affect your regular care.

If you change your mind about donating your bacterial (MRSA) isolates, just let us know that you do not want us to use your specimens for any new research. Please write to Dr Schuler and let her know. Dr Schuler will tell the people at the CF TDN that you have changed your

mind. All of your bacterial (MRSA) isolates from this study that are being stored at UNC Chapel Hill Microbiology lab will be removed. No new specimens from you will be saved for the Specimen Bank. Specimens that have already been given to researchers will continue to be used.

The number used to identify the leftover serum samples will not be linked to any information about you and therefore it is not possible for us to discard the specimen if you change your mind.

WHAT IF I HAVE QUESTIONS ABOUT THIS STUDY?

If you have questions about this research or about this study, please contact Dawn Baker, ARNP at (352) 273-5417

SUBJECT'S STATEMENT

Please read each of the choices below. Think about your choice. If you have any questions, please talk to your doctor or a nurse or a member of the research team. ***Initial*** *the line next to your choice.*

MRSA Bacterial Isolates:

____ I agree to allow my bacterial (MRSA) isolates to be stored indefinitely at the UNC Chapel Hill Microbiology Lab for future research about CF. The stored specimens will not be identified by my name.

____ I do NOT want to allow my bacterial (MRSA) isolates to be stored for future CF research.

Left Over Serum:

____ I agree to allow my left over serum to be stored indefinitely at the UNC Chapel Hill Microbiology Lab for future research about CF. The stored specimens will not be identified by my name.

____ I do NOT want to allow my left over serum to be stored for future CF research.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

_____ _____

Signature of Person Obtaining Consent & Authorization Date

Consenting Adults. You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this 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. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

_____ _____

Signature of Adult Consenting & Authorizing 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 hereby authorize the collection, use and sharing of protected health information for the person named below as described in sections 17-21 above. 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.

_____

Print: Name of Subject:

_____ _____

Print: Name of Legal Representative Print: Relationship to Participant:

_____ _____

Consent & Authorization Signature of Parent/Legal Representative Date