

ASSENT FORM

From 8/1/2012 Through 7/31/2013

*ejd*

**Study Title:** Early MRSA therapy in CF – culture based vs. observant therapy (treat or observe) (**STAR-too – STaph Aureus Resistance – treat or observe)**

**Protocol Number:** STAR-too-10K0

**What is research?**

We are asking you to be in a research study. Research is a way that we test new ideas. Research helps us learn new things.

Being in a research study is a choice. You can say “yes” or “no” to taking part in this research. We will still take good care of you no matter what you decide.

**Why are we doing this research?**

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.

This study is being done 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?

**What will happen in the research?**

If you join the study, you would have to come for a total of six study visits and have some tests and exams at those visits. The study compares two groups and you will be assigned by chance to one of the groups. One group, the **Treatment group** will be treated for 2-3 weeks for MRSA. The other group, the **Observed group**, will only get medicine if they have a flare up of their lung disease.

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 and/or have started menstruation 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 2 blood collection.

- **Spirometry**: You will be asked to take a test that measures your lung function by breathing. 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 as done when you come to clinic.
- **Study Cultures**. *Sputum cultures*: If you are able to cough up mucus into a cup, we would ask you to do this for the study. *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.
- **Medical Information**: We are asking you to share your medical information with study researchers. Your medical information will not contain any of your personal identification information, like your name and address.

These tests and exams help us to check on the safety of people in the study. We also use them to learn if a treatment is helping or not.

### **Research Study Visits:**

If you take part in all the study visits, you would need to come in for 5 or 6 visits and you would be in the study for approximately 6 months. The visits would last approximately 2 hours.

If you are assigned to the **observed group**, you will continue your normal CF care but you will not be treated for MRSA unless your doctor says so.

If you are assigned to the **treatment group**, you will be asked to do the MRSA treatment program in addition to your normal CF care. The program is described below:

- You will have to use a cotton swab to apply a special nasal ointment twice a day for 5 days.
- You will have to swallow some medicine (pills) twice a day for 14 days.
- You will have to use a special mouth wash twice a day for 14 days.
- You will have to take a shower or bath and then rub your skin with a special cloth once a day for 5 days.

### **What are the good things that can happen from this research?**

The research study will help us to learn more about MRSA in people with CF. It will not help you now. The study may help other people with CF in the future.



### **What are the bad things that can happen from this research?**

It is possible that your personal information, like your name, could accidentally be given to study researchers. We are taking steps for this not to happen, but it is a possibility.

- The blood collection may sting a bit and might leave a bruise
- Spirometry can cause wheezing and shortness of breath
- Medicine (pills) can sometimes cause an upset stomach or diarrhea.
- The throat swab can sometimes cause a little bit of coughing, discomfort or gagging
- The nose swabs can sometimes cause tickling or discomfort

### **What else should you know about the research?**

You may decide to be in the research study now and change your mind later. You can stop being in the research at any time. If you want to stop, please tell the research doctors or nurses.

### **Can I do something else instead?**

If you don't want to be in the study, you don't have to be. 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, here at the University of Florida MRSA is not treated unless there are symptoms.

### **Would I be paid if I do research?**

To thank you for participating in the study you would be paid for the visits that you complete. 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.

You should talk with your parents about how you would like to use this.



Take the time you need to make your choice. You can ask us any questions you have at any time.

\_\_\_\_\_  
Signature of Individual Obtaining Consent

\_\_\_\_\_  
Date

**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.

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\_\_\_\_\_  
Assent Signature of Participant

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Date