

UNIVERSITY OF CALIFORNIA IRVINE  
ASSENT TO ACT AS A HUMAN RESEARCH SUBJECT

**Mitochondrial Inborn Errors of Metabolism and ANT Defects in Mitochondrial Diseases; A Master Protocol**

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Name: \_\_\_\_\_

### **Why am I here?**

The doctors want to tell me about a study about children with mitochondrial diseases. They want to see if I would like to be in this study. Dr. Douglas Wallace and some other doctors are doing this study.

### **Why are they doing this study?**

They want to look at my blood and muscle to find out more about my disease. They will also use my blood and muscle to help other sick children like me.

### **What will happen to me?**

The doctors will discuss with me what tests they would like to do. Most of the time they will want only some blood but sometimes they may want to do other tests as well. The doctors will explain to me what test they would like to do and for what reason. Only if I want to do those tests will they be done. Nobody will be mad at me if I do not want the test.

1. The doctors may want to wipe inside of my mouth with cotton on a stick.
2. The doctors may ask me to breathe into a canister.
3. The doctors may want to pull two or three pieces of hair.
4. The doctors may want to take my picture.
5. The doctors may want to take pictures of my heart with a machine.
6. Only one time, doctor or nurse may want to take a little of my blood. It will be taken by a needle in my arm.
7. The doctors may want to study a little of my skin. For this they will numb a part of my arm and take a little piece (less than the size of a penny) from my arm.
8. The doctors may ask me for some of my pee to use in their study.
9. Dr. Sherif Emil may want to take some liquid from my back. I have to be very still. The doctor will either spray my back to help lessen the pain before they take liquid from my back. I feel cold first, and then my back will feel numb. Alternatively, the doctors will take the liquid from my back while I am asleep while he takes the muscle sample.



10. The doctors may need to study part of my muscle. Dr. Sherif Emil will make my leg numb or put me to sleep and then they will take a little piece of my leg muscle.
11. The doctors may ask if they can shine light on my arm, leg or head. This light will not hurt me, burn me or cause me pain. I should *not* stare directly at this light. I also might be asked to perform an exercise with my arm by lifting a weight or with my legs by raising my legs. I can stop these exercises if I get sore or I am too tired to continue. The doctors may want to put a blood pressure cuff on my arm. If it is too tight I should tell the doctor and they will take it off my arm.
12. The doctors may ask me to do other tests if they need more of my samples for their study.

### **Will the study hurt?**

Most tests done for this study will not hurt or hurt only a little bit. If the doctors need some fluid from my back or some muscle from my leg it will hurt. The stick from the needle and the wound from leg muscle surgery will hurt but the hurt will go away after awhile.

If I perform the exercises I might get sore but I can stop the exercises if I feel sore or too tired.

### **What are the risks of this study?**

I may feel some irritation when the doctors take my blood. I may also see a bruise, swelling, little blood on my arm, or even a mild infection where the doctor took my blood.

I may feel some irritation when the doctors take a little piece of my skin. I may also see a bruise, swelling, a little blood on my arm, or even a mild infection where the doctor took the skin.

I may feel some pain, bleeding, and/or get an infection on my leg where the doctor takes a piece of my leg muscle. If I need to have medication to sleep before the doctor removes a piece of muscle from my leg the medication might make me feel sick to my stomach or have a sore throat. This medication could also make me very sick, but the Drs. will be there to take care of me.

I may feel a little discomfort, have a really bad headache, have a drop of liquid leak from my back or possibly get a mild infection at the site where the doctor takes the liquid from my back.



The doctors may give me pills to stop my pain and infection.

I might feel sore from doing the exercises in my arm or leg. My skin might get irritated fastening the light probe to my skin. I won't stare at the light from the light probe or my eyes may hurt.

There may also be risks for me that the doctors are unable to predict at the moment.

**Will I get better if I am in the study?**

This study may or may not make me feel better. There is no proven treatment for my kind of illness known at this time. However, this study may help the doctors understand why I am sick. As a result, the doctors might find out something that will help other children like me later.

**What if I have any questions?**

I can ask questions any time. I can ask now. I can ask later. I can talk to the doctors or I can talk to someone else.

**Do I have to be in the study?**

I do not have to be in the study. No one will be mad at me if I don't want to do this. If I don't want to be in this study, I just have to tell them. If I want to be in the study, I just have to tell them. I can say yes now and change my mind later. It's up to me.

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Signature of Subject

\_\_\_\_\_  
Age (7-15 years)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Date

