



Children's Hospital Los Angeles
ASSENT TO PARTICIPATE IN A RESEARCH STUDY

Brain Blood Flow Study in people with and without sickle cell disease

Subject's Name: _____	
CHLA# [if applicable]: _____	Birth Date: _____

1. Dr. Wood and Dr. Coates are doing a research study about the brain and how it responds to the change in the air you breathe.
2. We are asking you to take part in this research because we want to learn more about how children with blood disorders respond to the change in the air they breathe while doing a MRI.
3. If you agree to be in this study, your participation will last up to 30 days and you will be asked to:
 - Lay still in the MRI machine while we look inside of your body. When you are in the MRI machine you will be asked to do is a special breathing test. We will give you a mouthpiece to breathe through and a clip that gently pinches your nose so that you have to breathe through a mouthpiece. We will ask you to breathe normally like you were sleeping. This will take about 2 hours to complete.
 - Have a small amount (3 tablespoons) of blood drawn from your arm
 - You may be asked to give some urine for the study. If you are asked for a urine sample, we will collect up to 3 teaspoons of urine.
 - You will be asked to wear 2 devices. One device will be attached to your chest by 2 pads and will measure how your heart is beating. The other device is attached to your wrist and one of your fingers. This device will measure your blood measure and oxygen levels. You will wear both devices for one day and then return them to us.

Return to CHLA on a separate day to complete written tests with a doctor. These tests will ask you questions about yourself and will measure your visual, verbal skills, memory and attention. Your parent will also be asked to complete information about you and themselves. This will take up to 4 hours to complete.

When you are in a research study, sometimes good things and bad things can happen:

4. Things that happen to children in research studies that make them feel bad are called "risks." Some of the bad things for this research study could be:
 - You might feel uncomfortable when breathing through the mouthpiece because your mouth may feel dry. While you are doing the breathing tests you may feel a little dizzy or like you have to breathe a little faster. You may also feel more alert or excited when the oxygen levels are increased. These changes in the oxygen levels will not hurt you and most people can't tell a difference.
 - It may hurt when a needle is used to collect a small sample of blood from you. Bruising, bleeding, swelling and the possibility of infection at the site of the blood may also happen.
 - You could be sensitive (allergic) to the tape used for the special stickers.
 - You may feel some discomfort during the written test with the doctor.
 - Someone may see your private information that is not part of the study team.

Not all of these things may happen to you. None of them may happen. Or things may happen that the doctors don't know about yet.

5. Things that happen to children in research studies that are good are called "benefits." This study does not benefit you, but it might help us learn things that might help us find better ways to take care of kids with sickle cell disease and other blood disorders in the future.
6. We will do everything possible to keep your information private.
7. Your parent(s)/guardian(s) will receive \$100.00 in cash for your being in this MRI study. They will also receive \$100.00 in cash for the pen and paper tests.

8. You do not have to be in this study if you don't want to. You may stop being in this study at any time. Remember, being in this study is up to you.
9. Please talk with your parents before you decide whether or not to be in this study. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say "yes," you can still decide not to do this.
10. You can ask any questions that you have about the study. If you have a question later that you didn't think of now, please write it down to help you remember. You can call me or ask me next time you see me.



323-361-8827 Study Office Number

11. Signing your name at the bottom means that you agree to be in this study.

Yes, I agree to be in this research study.

Signature of Subject

Date

Print Name of Individual Obtaining Assent

Signature of Individual Obtaining Assent

Date

Routing of signed copies of the assent form:

- 1) Give to the child (copy)
- 2) Give to the parent/legal guardian (copy)
- 3) Place in the CHLA Medical Record (copy)
- 4) Place in the Investigator's research files (original)