

**UNIVERSITY OF CALIFORNIA, IRVINE
ASSENT TO BE IN A HUMAN RESEARCH STUDY**

Form 2

Clinical Genetics of Craniosynostosis

Participating in this study is totally voluntary. Please read about the study below. Feel free to ask questions about anything that you do not understand before deciding if you want to be in the study. A researcher listed below will be around to answer your questions.

RESEARCH TEAM

Lead Researcher:

Virginia Kimonis, MD
Chief, Division of Genetics and Metabolism
Professor of Pediatrics
Department: Pediatrics
Telephone Number: (714) 456-5792
24-Hour Telephone: (714) 506-2063 (Pager)

Study Locations: UCI ICTS, UCI Medical Center, CHOC

WHO AM I AND WHY AM I MEETING WITH YOU?

I am Dr. Virginia Kimonis. My study team and I work at the University of California, Irvine in the Division of Genetics of the Department of Pediatrics. I want to tell you about a study that involves children like yourself or your brothers and sisters. I want to see if you would like to participate in this study.

WHY IS THIS STUDY BEING DONE?

I am studying why people are born with problems with the bones of the head. People with those problems or their brothers and sisters and parents may join this research study. I hope to find what causes these problems so that physicians can help other children who have the same problem.

Approved by IRB on: 04/22/11

HS# 2007-5631

Void After: 04/21/12

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WILL HAPPEN TO YOU IF YOU ARE IN THIS STUDY?

These things will happen if you want to be in the study:

1. Physical examination and measurements - we will listen to your heart, take your blood pressure, examine your eyes, and measure your head.
2. Brushing inside of the mouth with cotton swabs.
3. Taking photographs of your face and hands.
4. Taking blood from your arm.

If you join this study, the nurse will take a small amount of blood from your arm with a needle. Your mom or dad will be with you when we take the blood. If you want, we can use numbing cream so you do not feel the needle stick. If you need to have a surgery (not because of this study), I may take a bit of skin and/or muscle that otherwise will be thrown away. The study team will then study your blood or skin and/or muscle.

If for some reason we cannot get blood or if you prefer not to have the needle stick we can take some saliva from your mouth by touching your cheek with a tiny brush. In this case we will have just a little bit of material to study and we may need to collect more saliva from you in the future.

If you do not want us to take your picture, you can still be part of this study.

WILL ANY PART OF THE STUDY HURT?

If you decide to help me with this study you may have a needle stick to draw the blood. It may hurt a little to have the needle put in your arm, and it may leave a bruise.

WILL YOU GET BETTER IF YOU ARE IN THE STUDY?

You will not get better if you are in the study, but if you participate, the study team may learn more about your condition and may be able to help other kids with the same problem in the future.

WHO WILL KNOW THAT YOU ARE IN THE STUDY?

Only you, your parents and the researchers of this study will know that you are in this study.

DO YOU HAVE TO BE IN THE STUDY?

No, you don't. No one will get angry or upset if you don't want to be in the study. Just tell me. And remember, you can change your mind later if you decide you don't want to be in the study anymore. If you decide not to participate you will receive the same medical care as if you are participating.



DO YOU HAVE ANY QUESTIONS?

You can ask questions at any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else at any time during the study.

Here are the telephone numbers to reach me, Dr. Virginia Kimonis:

Telephone Number: (714) 456-5792

24 Hour Telephone: (714) 506-2063 (Pager)

Signature of Child

Age

Date

Signature of Researcher

Date

Signature of Witness

Date

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