

Subject's Name: \_\_\_\_\_  
Medical Record # \_\_\_\_\_

# Georgia Regents University

## Children's Assent Document (Ages 13 – 17)

**Protocol/Study Title:** Developmental Gene Discovery Project—Mapping and Identifying New Genes in Uterine and Vaginal Development Identifying New Genes Causing Birth Defects in Children

**Name of Principal Investigator (PI):** Lawrence C. Layman, M.D.

**PI address:** Georgia Regents University  
BB7514, 1120 15<sup>th</sup> St.  
Augusta, GA 30912

**PI telephone number:** (706) 721-3832

**Name(s) of Sub-investigators (sub-I):** Hyung Goo Kim, PhD.  
Lynn P. Chorich, M.A.  
Megan E. Sullivan, B.S.  
Viji Sundaram, M.D.

I am being asked to be in a medical research study I am being told about the study so I can tell the doctor if I want to be in it. They want me to ask any questions that I have about the study. The doctor will answer my questions.

Dr. Lawrence Layman is in charge of the study. The study is to try and learn more about how girls and boys grow up to become adult men and women. The study is also about how boys and girls sometimes do not grow up right or some parts of their bodies do not grow right.

They asked me to be in the study because I might have a problem developing from boy to man\_\_\_\_\_ or girl to woman\_\_\_\_\_. Or they have asked me to be in the study because someone in my family has not been able to grow up from a boy to a man or from a girl to a woman. Another reason they have asked me to be in the study is because someone in my family may have trouble having kids. They also may have asked me to be in the study because I might have parts of my body that do not work right.



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### Blood sample:

The main part of the study involves having the doctor examine my blood. He will look to see if he can find a reason for this problem. I will have about 2 tablespoons of my blood taken one time. The blood test will probably hurt some, but not for very long. My parents will have to take me to the doctor's office or to a laboratory for this to be done. This visit should last about one hour. The doctor will have to examine me to see how my body is growing but that will not hurt.

**The doctor may take a sample of my blood:** ☐ Yes \_\_\_\_\_ ☐ No \_\_\_\_\_

### Cheek swab:

I may be asked to rub the inside of my mouth with a piece of cotton. It will not hurt. DNA can be extracted from this. My DNA will be compared with either the DNA from someone who does not grow normally or from a person who does grow normally. These studies are important to see if there is a change in my DNA.

**My cheek swab may be used for the research study:**

☐ Yes \_\_\_\_\_ ☐ No \_\_\_\_\_

### Skin Sample:

A part of the study involves having the doctor examine the cells from my skin. He will look to see if he can find a reason for this problem. I will have a very little piece of skin taken one time. The skin test will probably hurt some, but not for very long. My parents will have to take me to the doctor's office for this to be done. This visit should last about one hour. The doctor will have to examine me to see how my body is growing but that will not hurt.

**The doctor may take a very small sample of my skin:** ☐ Yes \_\_\_\_\_ ☐ No \_\_\_\_\_

### Consent for tissue collection:

I may be asked to allow a small piece of tissue (relevant to the research) that would otherwise be discarded during surgery to be collected for use in the study. My DNA, RNA, and/or protein will be extracted from the tissue and compared to an affected person or healthy control. These studies are important to establish if a real gene variant is confirmed in someone with a developmental disorder.

For subjects: my tissue DNA/RNA/protein will then be studied to see if there are changes that may be the cause of the disease or be a marker for the disease. This might help researchers find the responsible gene. For healthy controls: my tissue DNA/RNA/protein will be used to compare with that of a subject.

**The doctor may take a very small sample of discarded tissue for the purposes of the research study:**

☐ Yes \_\_\_\_\_ ☐ No \_\_\_\_\_

### Photograph Consent



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I may be asked to have my picture taken for this medical research study. I can tell them if I want to have my picture taken for the study or not. They want me to ask any questions that I have about having my picture taken. The doctor will answer my questions. The picture is to show special things about my condition related to the medical research study or because someone in my family may have trouble having kids. My picture may be put in a report that tells about my condition. No one will know my name if the picture is printed in a study report. My picture will be kept in a safe place.

**The doctor may take my picture:** ☐ Yes \_\_\_\_\_ ☐ No \_\_\_\_\_

### **Voluntary participation**

I do not have to be in this study. I can stop at any time. Stopping or not being in the study will not upset anyone. I can and should let my parents, doctors and doctor's assistants about any part of the study that I don't like. The doctors and assistants will answer my questions about this study at any time. My parent/guardian knows about this study. They said that I could be in the study.

I have read this paper. It will be explained to me. I will have a chance to ask questions. The questions will be answered so that I can understand. If I have more questions, my parents or I can call Dr. Layman at (706) 721-3832. I will participate in the study.

\_\_\_\_\_  
 Subject's Name (print)

\_\_\_\_\_  
 Subject's Signature

\_\_\_\_\_  
 Date

\_\_\_\_\_  
 Time of Subject's Signature (00:00)

\_\_\_\_\_  
 \*Parent/Guardian's Name (print)

\_\_\_\_\_  
 \*Parent/Guardian's Signature

\_\_\_\_\_  
 Date

\_\_\_\_\_  
 Time of Parent or Guardian's Signature (00:00)



Approved on:	10/12/2015
Expires on:	06/23/2016
Study number:	611184-8

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\*The individual above verifies that he/she is the natural parent and/or legal guardian of \_\_\_\_\_ and as such has the legal authority to consent to the study outlined above

\_\_\_\_\_  
Witness' name (print)

\_\_\_\_\_  
Witness' signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time of Witness' Signature (00:00)

### INVESTIGATOR:

I acknowledge that I have discussed the above study with this participant and answered all of his/her questions. They have voluntarily agreed to participate. I have documented this action in the subject's medical record or source document. A copy of this signed document will be placed in the subject's medical record or source document. A copy of this document will be given to the subject or the subject's legally authorized representative.

\_\_\_\_\_  
Printed name of investigator obtaining consent

\_\_\_\_\_  
Signature of investigator obtaining consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time of Investigator's Signature (00:00)

