

Subject's Name: _____
Medical Record # _____

Georgia Regents University

Children's Assent Document (Ages 7 – 12)

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.

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I am being asked to be in a medical research study. The doctors and nurses are telling me about the study. I can tell them if I want to be in the study or not. 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.



STUDY

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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.

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 will last about an 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. This will not hurt. The doctor will compare this with someone who does grow normally. These studies are important to see if there is a change in my body.

The doctor or my parents may do a cheek swab in my mouth:

☐ 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 will last about an 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:

If I am having an operation, I may be asked to allow a small piece of tissue that would otherwise be thrown away during surgery to be collected for use in the study. This will not hurt. These studies are important to see why there is a change in my body.



STUDY

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The doctor may take a very small sample of tissue while I am having an operation for this research study:

☐ Yes _____ ☐ No _____

Photograph Consent

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. I can tell them if I do not want to have my picture taken for the study. 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 any time I want to. If I do stop or if I do not want to be in the study, it's okay. No one will be mad at me. I can tell my parents, doctors and nurses about anything in the study that I don't like. They will answer my questions. My parent/guardian knows about this study. They said that I could be in the study.

I have read this paper. They will explain it to me. I will have a chance to ask questions. They will answer the question so that I can understand. If I have more questions, my parents or I can call Dr. Layman at (706) 721-3832. I will be in the study.

 Subject's Name (print)

 Subject's Signature

 Date

 Time of Subject's Signature (00:00)



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

Subject's Name: _____
Medical Record # _____

*Parent/Guardian's Name (print)

*Parent/Guardian's Signature

Date

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

*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 source documents or research chart source documents, as applicable. A copy of this signed document will be placed in the subject's medical record or research chart, as applicable. 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)

