

Assent Statement (Ages 12 – 17)

Study Title: Genetic Studies of Constitutional Disorders

Study number: AAAS7948

Anticipated number of Subjects: 13,500

Study duration: 1 hour

Principal Investigator: Dr. Ali Gharavi

Contact number: 212-851-4927

Email: cpmg_info@cumc.columbia.edu

You are being asked to take part in a research study. This form explains why we are doing this study and what you will be asked to do if you choose to be in this study.

Please take time to read the form carefully and discuss it with your parents. Ask us if there is anything that is not clear. Take time to decide whether or not you wish to take part in this research study.

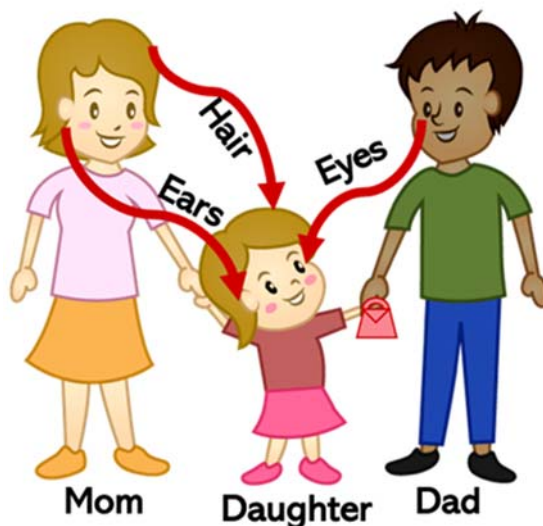
The purpose of this research is to learn more about the genetic material (DNA) of individuals with medical conditions.

1. Why am I being asked to participate?

We are asking you to be in a research study. Research is a way to test new ideas and help us learn new things. In this study, we want to learn more about what causes sickness and why some diseases may run in families. You are being asked to participate because we want to find out why you or your family member is sick.

2. What are the researchers studying?

This is a genetic study. A genetic study looks at a person's DNA. A person's DNA has information that tells their body how to work. We all have differences in our DNA that determine the color of our hair or influence how tall we are. Sometimes, a person has a difference in their DNA that causes their body not to work correctly and might cause them to become sick. We want to find out what kind of differences in DNA cause people to develop certain diseases.



Learn more about genetics:

<https://www.amnh.org/explore/ology/genetics/what-s-the-big-idea-about-genetics2>

3. What would I have to do in this study?

If you agree to be in this study, you will be asked to do the following:

~ Answer some questions about your health history and your family health history. We will look at your medical records.

~ Give a sample of your DNA. We will probably do this by drawing blood (about 3 teaspoons) from your arm. We will then store these samples.

~ We will also ask you and your parent if you are willing to come back to see us, and give other samples (like blood, saliva, or a cheek swab).

4. What information will I learn?

We might learn information about your DNA that will be important for your health. This information could tell us why you developed a sickness that you already have. If we find this information, you and your parent have the choice of learning or not learning what we found.

We could also find that you have an increased risk of having a different sickness in the future. You and your parent have the choice of learning or not learning these results too. You and your parent should discuss what type of results you would like to learn from this study.

If we find any of this genetic information and you want to learn about it, we will ask you to come back for a visit to give another sample of your DNA for a certified genetic test.

If we are not able to reach you, we will not return any future genetic results to you.

5. Benefits (How may it help you?)

A “benefit” is something good or helpful. There are many different ways research can benefit people: feeling better, new medicine, or having new information you did not know before.

There is no direct benefit to you for being in this study, but the results may help us learn more about why children your age develop certain sicknesses. We will use this to help children and families with sicknesses in the future.

6. Risks (Will it hurt?)

In this research study, it may hurt when the needle is put in your arm to take blood. You will feel a tiny pinch and your arm may feel sore for a few minutes.

7. Privacy (Who will know about it?)

We will keep the information from your visit, including your name, your medical information, and your genetic information. We will use it to do research into why you, your family member, or other people have conditions like yours. Information that we get from you may also be shared with other researchers in the future, but only after your name has been removed. Information from this study is given a code number so that researchers who are not working on this particular study will not be able to identify you. The code will be stored safely at Columbia University.

When we are finished with this study we will write a report about what was learned. This report will not include your name or that you were in the study.

8. Do I Have To Be In This Study?

You do not have to be in this study. It’s up to you. No one will be upset with you if you don’t want to

participate. If you say yes now, you can still change your mind later if you want to stop. Please talk to your parents about the study before you decide.

9. Can I ask questions?

You can ask any question at any time. If you are not sure about something, you can talk to your doctor or your parents. You can call us at 212-851-4927 or email us at cpmg-info@cumc.columbia.edu at any time if you have more questions about the study. This form is yours to keep.

10. What do I have to decide?

If you agree to be in the study, we will ask you to write your name on this form. One of your parents will write their name and sign a separate form. Writing your name on this form is a way of showing that you understand what we are asking you to do and that you agree to participate. Remember that you do not have to participate if you do not want to. Do not sign this form if you do not want to participate. Just tell us that you do not want to take part in this study. Even if you agree to participate now, you can change your mind later.

11. What will happen when I turn 18 years old?

When you turn 18 years old, you can contact us or we will try to reach you and invite you to agree to the study again and sign the form signed by your parent today. Therefore, it is important that you keep us up to date with your phone number or address changes.

If you want to be in this research study, please sign below. If you do not want to be in this study, do not sign this paper.

STATEMENT OF ASSENT

I have read this form and talked about this research study with the researcher and with my parent(s). My questions were answered.

Minor Study Participant

Print name of Minor

Signature of Minor

Signature Date ____/____/____

Person Obtaining Assent

Print name of Person Obtaining Assent

Signature of Person Obtaining Assent

Signature Date ____/____/____