

PAPERWORK REDUCTION ACT STATEMENT

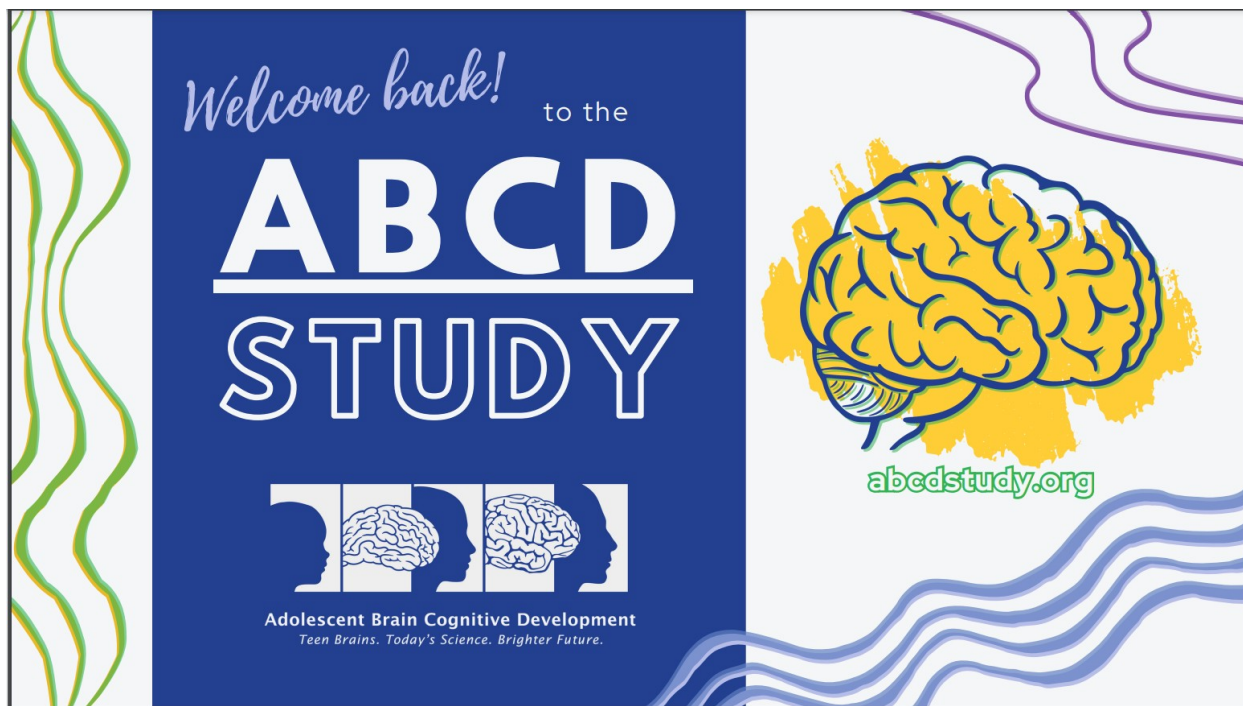
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Instructions

Thank you for being part of our feedback team! We understand your time is important, so we want you to read through the materials before your scheduled interview, to make the most of the discussion time. Please read over the following visuals to get familiar with them before your session.

We look forward to hearing your feedback during your scheduled interview!

Draft Visual Consent Form



GOALS OF THE ABCD STUDY

ABCD is the largest study of its kind in the US, following over 11,000 kids as they go through adolescence.

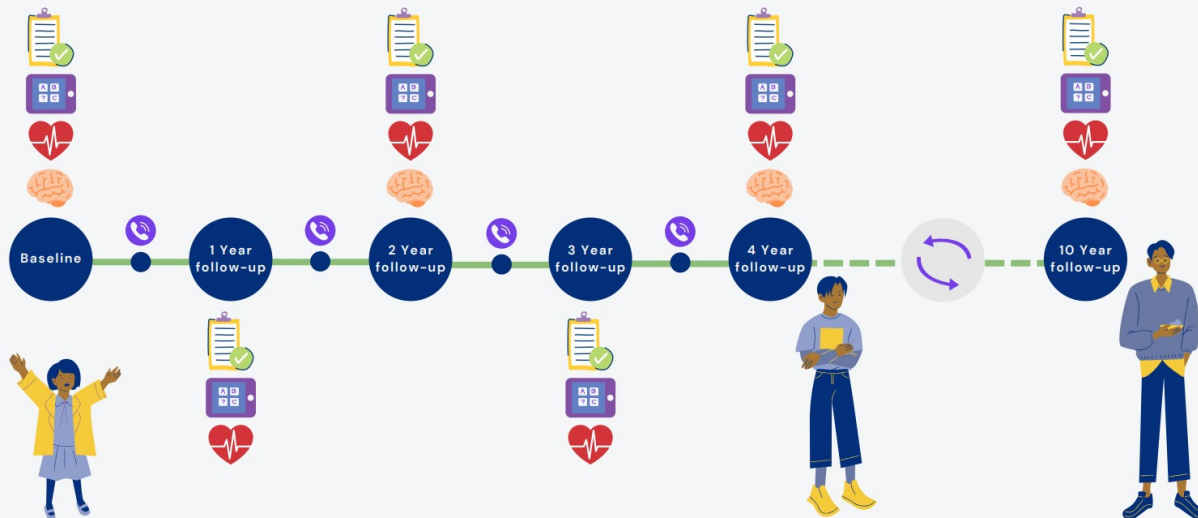
The study will help scientists answer questions like:

- What does the trajectory of "typical brain development" really look like?
- How do experiences & environment (like sleep patterns, screen time, sports, substance use, social relationships, & many more) interact with each other and with the brain & biology?
- What effects do these factors have on brain development, health, & other outcomes?

Many others—ABCD'S Open Science model means any scientist can access the data to explore their research questions!



ABCD STUDY TIMELINE



STUDY PROCEDURES



Questionnaires & Interviews

- Contact Information
- Mood & Behavior
- Culture & Relationships
- Substance Use
- Physical & Mental Health

Cognitive Assessments

Games designed to measure things like:



- Memory
- Language
- Attention
- Problem solving
- Decision making

STUDY PROCEDURES

Biological Samples & Measurements



Saliva

Hormone levels
Substance use



Hair

Substance use



Blood Draw

Genetics
Health Indicators

If you choose to do the blood draw, you will receive extra compensation.

Breath

Intoxication



Urine

Substance use



Blood Pressure



If you are under the influence of non-prescription drugs or alcohol, we might need to reschedule your study visit (just because it would affect how your brain works!)

MRI BRAIN SCAN



 1½ hours

Brain Images

- Structure
- Activity while you are at rest
- Activity during different games



Safety

MRI is very safe,
but it is loud.

MRI uses strong magnets and radio waves to create images, so you might not be able to do the scan if you:

- Have braces
- Have an implanted metal device (like a pacemaker or cochlear implant)
- Are pregnant



TECH SUB-STUDIES



Fitbit

Heart rate
Physical activity
Sleep



EARS App

Screen time & app use
How much you type in
different apps



Both these sub-studies will have you download an app on your phone for 3 weeks.

You don't need to do anything different besides wear the Fitbit, keep the EARS app open in the background, and periodically sync your data!

If you complete one or both of these sub-studies, you will get extra compensation.

CONFIDENTIALITY

We don't tell anyone outside the study (even your parent) about your answers to any questions.



EXCEPTIONS

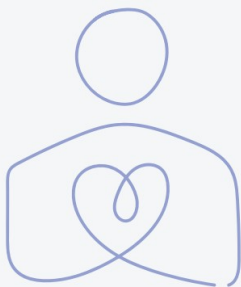
If someone is at risk of being harmed, we are required by law to try to keep them safe.



If we learn you plan to harm yourself or others, or if a child or elder is being abused, we may need to tell someone (such as the authorities) to make sure people are safe.

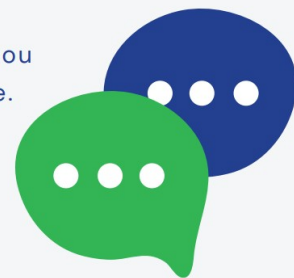
VOLUNTARY RESEARCH

You never have to do any part of the study you don't want to do!



Let the researcher you're working with know if you want to skip a question, game, or anything else.

You can also stop participating or take a break from the study anytime if you want.

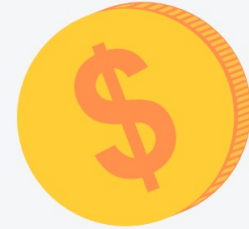


It's important to us that you feel comfortable & safe during the study!

STUDY COMPENSATION

We appreciate the time and effort you spend contributing to our science!

The amount and method of your payment for each study visit can be found in your consent form.



Some parts of the study give you extra payment:

- Blood draw
- MRI money game
- Fitbit sub-study
- Mobile Tech sub-study

Draft Consent Form to Get Hereditary Disease Risk Results

The ABCD Study Consent to get Hereditary Disease Risk Results

When you joined the program, you signed a form that says you agree to let scientists study your DNA for research, but that no other genetic information would be shared with you. Recently, a new genetic assessment was added to the research plan, which gives us the opportunity to return some genetic information back to you.

Now we want to know if you want the ABCD Study to tell you if we find DNA changes related to health and disease risk for you. These are your Hereditary Disease Risk results. The following screens explain:

1. The choice you have about learning your results.
2. Details about different kinds of DNA changes.
3. How we will check for them and how long it will take.
4. How you can learn about your results.

There are benefits and risks to getting your Hereditary Disease Risk results, and we want you to make the best decision for yourself. Before you decide, please review the following information. At the end, you will be asked to decide if you want these results. You can decide:

- Yes (it may take a few years to receive results)
- No
- I'm not sure right now
- I would like to speak with a genetic counselor before making a decision

What are “DNA Changes”?

All human beings share more than 99% of their DNA with each other. The tiny bit that is different is part of what makes each of us unique. Things like our hair color and eye color depend on the bits of our DNA that are different between human beings. We call these our DNA changes. We know what some DNA changes mean, but we still have a lot to learn. For example, we are still learning what role DNA plays in most health conditions. But for a small number of things, we already know a lot about the role DNA plays.

We know that certain changes in our DNA can affect our health. For example:

- Certain DNA changes can increase our risk for a few specific health conditions. This could include some cancers and types of heart disease.
- Certain changes in our DNA can increase the risk of passing specific health conditions on to our children, even if we don't have those conditions.

The more we study our DNA, the more we will learn what DNA changes mean about us. The ABCD Study will have specially trained scientists look at your DNA for changes related to hereditary disease risk.

What will my Hereditary Disease Risk results tell me?

Your results will have information about your DNA and whether you may have a greater risk for developing some serious health conditions, such as certain kinds of cancer or heart disease.

About 2 out of 100 people will get a DNA result that shows that they have a higher risk of developing a disease. For example, a small number of people may find out they have a version of the BRCA1 gene that increases their risk for some kinds of cancers, like breast cancer.

We will use the current list developed by the American College of Medical Genetics. It was specially designed by a group of genetic experts to include DNA changes that are very likely to cause disease or health conditions for which medical treatment is available and for which early diagnosis is critical for effective treatment. It does not include disorders that would typically be diagnosed by a doctor or disorders where a lifestyle change would be the main treatment (e.g., avoiding tobacco use).

How will I get my results?

If we find a change in your DNA that increases your risk of a health condition, we will try to contact you directly. We will help you make an appointment with an ABCD Study genetic counselor. They will tell you your results. They will answer your questions. They will send you a report. They can also send a report to your health care provider. If you want, they will help you find a health care provider in your area.

Most people (about 98 out of 100 people) will get a report that says ABCD did not find anything significant for their health in the DNA we looked at.

Research that uses your samples and information may not be finished quickly. There is a chance that you will not hear from any researchers. If you do not hear from anyone on the ABCD Study:

- Your sample may not have been studied yet OR
- You may not have any of the gene changes that we are studying at this time

What are the risks of getting my Hereditary Disease Risk results?

The next three screens will review some important information to consider when making a decision of whether to receive Hereditary Disease risk results.

- If your results show an increased risk of developing a serious health condition, you will be given the option to discuss these results and their consequence with a licensed genetic counselor, free of charge.
- A genetic counselor will not provide treatment; however, they may work with your doctor or health care provider to recommend changes to your medical care. Those changes could cost more than your current care. You can decide what care is right for you. If you do not have a primary health care provider, your site can provide you with a list of local health care resources to contact.

Could learning about my hereditary disease risk affect my insurance?

- **Your health insurance will not be affected.** Health insurers **cannot** use DNA information to decide if they will cover you, change your coverage, cancel your coverage, or charge you more.
 - A federal law stops them from using DNA information in this way.
- **Disability, life and long-term care insurance is different.** In most places, disability, life and long term care insurers **can** use DNA information to decide if they will cover you and how much to charge you.

How could learning about my hereditary disease risk affect me emotionally?

- You could get information you weren't expecting in your results. For example:
 - You might discover that you are at risk for a disease that has not been seen in other members of your family
- If you have a certain DNA change, your blood relatives might have it too. They may or may not want to know this information. This could be a particularly important consideration for those with siblings, twins, or siblings from a multiple birth.
- Your results could make you worried or confused. For example:
 - You may be afraid of passing a hereditary disease risk on to your children.
 - Your results may make you wonder if you are related to a family member in the way you thought. Keep in mind that DNA results are not always the same for all blood relatives

If we find your DNA puts you at risk for developing a serious condition we will place you in contact with a licensed genetic counselor, free of charge, with whom you can discuss concerns or questions.

What are the benefits of learning about my hereditary disease risk?

You could learn that there is something very important for your health in your DNA. Knowing this could help you work with your doctor or health care provider to prevent disease or to detect it early. We will only inform you about DNA results where there is an established medical treatment to reduce risk. In some cases, knowing this information can be lifesaving.

You could discover something that could help explain the history of a health condition among your blood relatives.

Having this information could help you talk with your family. Everyone's DNA is different, but sharing your DNA results with your blood relatives can help them think about their own health. They can consider if they want to get tested themselves. This could end up helping them stay healthy.

You will be able to talk to a licensed ABCD genetic counselor about your test results. Talking to an ABCD genetic counselor is free.

What are the limits of my Hereditary Disease Risk results from the ABCD Study?

- The ABCD Study is a research program. We analyze DNA for research purposes. If you receive health-related DNA results from the ABCD Study, those results are not a diagnosis. Only a doctor or health care provider can diagnose you with a health condition and determine how to treat you. If you are concerned about your DNA results, it's always good to discuss them with your doctor or health care provider.
- These results do not tell you whether you have or will get a disease. Many factors can contribute to whether or not you develop a disease. Your DNA may contribute, but it is not the only factor.
- We will not inform you of DNA results that put you at risk for disorders for which there is no current treatment.
- There are a lot of genes that can affect disease risk and we won't look at all of them. There could even be something we couldn't see or can't understand in the genes that we did look at. Scientific understanding of DNA and diseases is always growing.
- These results will be based on current scientific understanding. There is a chance they could be wrong. As we learn more information, ABCD could look at more genes in the future or look at these genes again to provide new results.

What are my choices?

It is your choice whether you want to get your Hereditary Disease Risk results. You can always change this decision at a later stage.

If you say "Yes, I want my Hereditary Disease Risk results":

- One of our specially trained scientists will look closely at some of the genes in your DNA related to serious health conditions, like certain kinds of cancer and heart disease. They will generate results for you based on what they find.

If you say "No, I do not want my Hereditary Disease Risk results":

- You will not be contacted about any potential findings from your DNA that relate to serious health conditions

If you say "I'm not sure right now":

- You can come back and decide later

If you say "I would like to speak with a genetic counselor before making a decision":

- You will be contacted by a genetic counselor to discuss potential results before deciding if you would like to receive DNA results

We will send you messages when new result types are available

Would you like to get your Hereditary Disease Risk results?

Yes, I want my Hereditary Disease Risk results.

You will be able to see your results once they are ready, which may take a few years to generate. ABCD will contact you when your results are ready. If we find your DNA puts you at risk for a Hereditary disease we will place you in contact with an expert genetic counselor (free of charge) to discuss results.

No, I do not want my Hereditary Disease Risk results.

You can always change your decision later.

I'm not sure right now.

If you are not ready to decide, you can choose to get these results later.

I would like to speak with a genetic counselor before making a decision.

We will place you in contact with an expert genetic counselor (free of charge) who can answer your questions before you make a decision

You can always change this decision at a later stage.

Would you like to speak with a Genetic Counselor?

An expert genetic counselor may be able to assist in answering questions you may have about potential DNA results. Would you like to speak with a genetic counselor, free of charge, *before* receiving any DNA results?

- Yes, I would like to talk with a genetic counselor *before* receiving results

This may give you an opportunity to discuss and further understand what DNA results you may receive.

- No, I would *not* like to be contacted with a genetic counselor *before* receiving results

I would not like to speak with a genetic counselor to discuss potential findings from DNA.

Regardless of your answer here, if you have decided to receive your Hereditary Disease risk results and we find your DNA puts you at risk for a serious health condition, you will automatically be placed in contact with a free genetic counselor *after* you receive your results to discuss what this means for you.