

Study to Explore Early Development

Informed Consent Form Cheek Swab For Biological Mother of Child Participant

Public Reporting Burden Statement

Public reporting burden of this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0741)

Center for Autism and Developmental Disabilities Research and Epidemiology Study to Explore Early Development

You are invited to be in a research study being done by *<or being done with>* the Centers for Disease Control and Prevention (CDC). CDC is a federal agency that works to improve the health and safety of the general public. This data is collected under the authority of Section 301 of the Public Health Service Act. The study is called The Study to Explore Early Development. It is being done by 6 different sites in the US. *<Location>* is one of the sites taking part in the study.

The study in *<location>* is being done through a partnership with schools in the *<location>* area and local healthcare providers. *<Site specific...The <federal department of education> gave <CDC> permission to work with the schools.>* The partnership with schools, doctors, and health clinics is important to help *<site>* learn more about child development.

What is the purpose of the study?

This is a study on child development. One focus of the study is to look at possible causes for autism. We know that many children have autism and other related disabilities. However, we want to learn more about characteristics of these children. We also want to learn more about risk factors and possible causes.

Most of the risk factors that we are looking at are things that occur during pregnancy or in the early stages of a child's life. The results may lead to better services and treatments for children with autism and other related disabilities.

What will I have to do to be in the study?

You and your child will be asked to complete several different parts of the study. This consent form is only for the cheek cell sample. Another consent form is also included in this packet for you to read. This consent form explains all other parts of the study.

Why are you collecting cheek swabs?

Many children have developmental disabilities. Some people think that these disabilities may be related to genes. We are asking you to brush the inside of your cheek so that we can collect cells from the cheek lining. We will get DNA from these cells so that we can study genes.

How will you collect cheek swabs?

We have given you 3 special brushes. We ask that you use these to brush the inside of your cheeks. Specific instructions are included with the brushes. It will take about 10 minutes. There is also a small chance we may ask you to do this twice. We will give you three more brushes. We will ask you to repeat the steps. This can happen for 2 reasons: 1) if the lab has a problem doing the tests for genes on the first samples you give and 2) a small group of parents will be asked to provide another sample to test how our lab is doing. The parents who are chosen to give more samples will be picked at random (through something like a coin toss).

What will happen to the sample after you collect it?

All samples will be sent to a central study laboratory and repository. DNA will be taken from the cells on the brush. The DNA will be tested for genes. These genes may be related to autism and other developmental disabilities.

We would like to store any samples that are left over after we have finished our study. We would like to store samples in case future studies can be conducted that may answer important new questions. We ask that you to allow us to keep these samples at the central lab. We plan to keep the samples indefinitely.

If you do allow us to store your samples, you can choose to store the sample with or without your study ID. No one at the lab will have your personal information (such as your name or address). The study ID is a number we give you when you agree to be in the study. Only the people working on the study will have access to your personal information. All study forms and samples will only have your study ID. The personal information will be kept in a database that is kept on a secure computer (password protected) in the study manager's office. If a hardcopy list is printed linking your study ID and identifiers this will be maintained in a locked file cabinet in the study manager's office. Please see the frequently asked questions about biologic samples for more information about your study ID and your privacy.

What are the risks of giving a cheek swab?

There are few risks involved with giving a cheek swab. In rare instances people feel discomfort when brushing the cheek.

What are the benefits of giving a cheek cell swab?

You are not expected to get any direct benefits from giving a cheek swab. However, the sample may help us learn more about possible causes of autism and other developmental disabilities.

Is this going to cost me anything?

No costs are involved with giving a cheek cell swab. You will not be charged for any of the tests that we do.

Will I be reimbursed in any way?

We realize that your time is valuable. You will be compensated for the time and effort it takes to be in the study. Please see the comprehensive consent form in the enrollment packet for a description of study compensation.

Can I find out about the results of genetic testing?

Little is known about which genes and other biologic substances are related to autism. The results from this study will only be initial leads. The same findings will have to be seen again in other studies before they can be considered useful to a particular child or family. The labs that do our tests are research labs. These labs are not always approved for doing tests that are normally done on clinical patients. Because of these reasons, you will not receive individual results from the biological samples that we collect for this study.

We will send you a study newsletter up to two times per year. It will be mailed directly to your home. The newsletter will tell you about study results including genetic and lab results. You can discuss any of these findings with your medical provider. It is important to remember that it will be some time (up to several years) before all results are available.

Do I have to give a cheek swab?

You do not have to provide a cheek swab in order to be in the study. The decision to give a sample is up to you. Your participation is voluntary. There is no penalty if you do not want to be in this part of the study.

Will the information I give be kept private?

The information you give will only be used for this study. Your information will remain confidential unless otherwise required by law. We will never use your name or your child's name in any report. The information you give will always be combined with information from all other participants.

You will be given a study ID. This study ID will be the only information on all study forms. Your name or other identifying information will not be on the study forms. Only people working on the study will have access to your personal information. Results from the study will only be linked to your study ID, not your name. This link will be maintained on a database that is kept on a secure computer (password protected) in the study manager's office. If a hardcopy list is printed linking your ID and identifiers this will be kept in a locked file cabinet in the study manager's office.

You can choose to store your biologic sample with or without a link to your name. Please see the form entitled ‘frequently asked questions about biologic samples’ for details of what this means.

Consent forms will be kept in locked file cabinets. Only study staff will have access to your consent forms.

We may share some study data with other researchers. They will be approved by our team. We will not give them any information that could identify you. Other researchers will not have access to the list that links your study ID with your name.

Because sensitive information is collected in this study, <site> received a ‘Certificate of Confidentiality.’ This means that any information that <site> has that identifies you or your child will be used only for this project. It cannot be given to anyone else unless you give your written consent.

Who can I call if I have questions?

If you have questions about the study you can call <PI or project coordinator> at <phone number>. If you have questions about your rights as a research participant you can call <local contact> at <local number>.

If you feel you have been harmed by participating in this research study, please contact << PI or Project Coordinator>> at <insert phone number>.

Informed Consent Statement:

I have been told about this part of the study. I know what is expected of me. I was allowed to ask questions. I had all my questions answered.

PLEASE CHECK ONE.

- I AGREE to provide a cheek swab.
- I DO NOT WANT to give a cheek swab.

PLEASE CHECK ONE.

- I AGREE to have my cheek swab stored for future research studies. The cheek swab will be stored at the central repository of the study with my study ID. (WITH identifiers – you will be contacted for future studies)
- I AGREE to have my biologic samples stored for future research studies without my study ID. (WITHOUT identifiers – you will not be contacted for future studies).
- I DO NOT WANT my biologic sample stored for future research studies (samples will be destroyed after the study is over).

Permission to Enroll Child:

I have been told about the study. I know what is expected of my child. I was allowed to ask questions. I had all my questions answered. I give permission to enroll my child in this study.

Signature of mother/legal guardian

Date

Printed name (mother/legal guardian)

Printed name (child)

Permission to Enroll Self:

I have been told about the study. I know what is expected of me. I was allowed to ask questions. I had all my questions answered. I voluntarily agree to enroll in this study.

Signature of biological mother/legal guardian

Date

Printed name (biological mother/legal guardian)