

# **Study to Explore Early Development**

## **Informed Consent Form Saliva Collection For Biological Parent Participant**

## **Study to Explore Early Development**

You are invited to be in a research study being done by 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 5 different sites in the US. *<Location>* is one of the sites taking part in the study.

### **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?**

Families enrolled in this study will be asked to complete several different activities. This consent form is only for the saliva sample, which is collected from the child enrolled in the study and both biological parents.

### **Why are you collecting saliva?**

Many children have developmental disabilities. Some people think that these disabilities may be related to genes. We are asking you to provide a saliva sample using a kit we will give you. We will get DNA from the saliva so that we can study genes.

### **How will you collect the saliva sample?**

We have a special kit with a tube that you can fill with saliva using one of two methods. One way is to directly spit into the tube. If you cannot or choose not to spit, you can use a small sponge to soak up saliva from your mouth. We will give you specific instructions for the method you choose. It can take about 10 minutes depending on how much saliva you make. There is also a small chance we may ask you to do this twice. If so, we will give you another kit. We will ask you to repeat the steps. This can happen if the lab has a problem doing the tests for genes on the first samples you give.

### **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 saliva. 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 saliva sample?**

There are few risks involved with giving a saliva sample. In rare instances people feel discomfort when using the soft sponge in their cheek.

**What are the benefits of giving a saliva sample?**

You are not expected to get any direct benefits from giving a saliva sample. 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 saliva sample. You will not be charged for any of the tests that we do.

**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.

**Do I have to give a saliva sample?**

You do not have to provide a saliva sample 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.

**Certificate of Confidentiality**

All answers that you give will be kept private. 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. But under law, we may report to the state suspected cases of child abuse or if you tell us you are planning to cause serious harm to yourself or others.

**Who can I call if I have questions?**

If you have questions about the study you can call <site PI or project coordinator> at <phone number>. If you feel you have been harmed by participating in this research study, please contact <site PI or project coordinator> at <phone number>. If you have questions about your rights as a research participant you can call the <site IRB office contact> at <phone number>.

**Informed Consent Statement:**

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 parent

\_\_\_\_\_  
Date/Time

\_\_\_\_\_  
Printed name parent

PLEASE INITIAL ONE for you:

- I AGREE to provide a saliva sample.
- I DO NOT WANT to give a saliva sample.

PLEASE INITIAL ONE for your sample:

- I AGREE to have my biologic sample stored for future research studies. The biologic samples 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 sample 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).

## **National Database for Autism Research (NDAR) and Database for Genotypes and Phenotypes (dbGaP)**

There are national efforts to share information from studies to help speed the progress of scientific discoveries. Two of these efforts include the National Database for Autism Research (NDAR) and the Database for Genotypes and Phenotypes (dbGaP). These two databases are managed by the National Institutes of Health (NIH) which is part of the U.S. Department of Health and Human Services.

### **National Database for Autism Research (NDAR)**

The NIH NDAR database allows researchers studying autism to easily share and pool research information with each other. By making this easier, researchers hope to learn new and important things about autism more quickly than they could without NDAR. For more information, go to <http://ndar.nih.gov/index.html>.

### **Database for Genotypes and Phenotypes (dbGaP):**

The NIH dbGaP database has genetic data from many studies. Scientific researchers who want to use these data must apply to NIH for permission to use these data and access the data in a secure way. For more information, go to <http://www.ncbi.nlm.nih.gov/gap>.

With your permission, we would like to submit some of your genetic information to NDAR and dbGaP. We would not submit identifying information like name, address and phone number to these databases. SEED will remove identifying information such as your name, address, and phone number, and replace that information with a code number. If you agree, de-identified parts of your genetic information will be shared with these two scientific databases maintained by the National Institutes of Health. These databases are restricted and can only be accessed by approved researchers nationwide who have filed an application with the NIH to obtain access to your study data for research purposes.

Nobody will be able to know just from looking at a database that the information belongs to you. However, because your genetic information is unique, there is a small chance that someone could trace the information back to you or close biological relatives. The current risk of this happening is small, but may grow in the future as new ways of tracing the information back to you or your close biological relatives are developed. Thus, the risk that your privacy would be breached may increase over time. Researchers who access your genetic and clinical information will have a professional obligation to protect your privacy and maintain your confidentiality.

The decision of whether or not to allow genetic information about you that is collected in SEED to be shared with other researchers through access to these national scientific databases is completely up to you. There will be no penalty to you if you decide not to allow this information to be shared with NDAR or dbGaP. Your child's school and healthcare services will not be affected if you decide that you do not want to share your information. Also, you and your child can still be in this study if you decide that you do not want to share your information with NDAR or dbGaP.

We ask you to choose whether you will allow us or not to share your data with NDAR or dbGaP. Consent forms will be kept in locked file cabinets. Only a few specific study staff will have access to your consent forms.

### **Informed Consent Statement**

#### **National Database for Autism Research**

You may decide now or later that you do not want to share your information with NDAR. If you give permission for us to share information with NDAR now and want to end this authorization later, contact <site PI>, at (xxx) xxx-xxx. However, any data already shared with NDAR cannot be taken back. Please check your answer below. Take time to consider each option, and ask any questions you need to ask to help you understand them.

*Please initial one*

I agree for my genetic information to be shared in a restricted manner and without identifying information with NDAR.

I do not want my genetic information to be shared with NDAR.

#### **Database for Genotypes and Phenotypes**

You may decide now or later that you do not want to share your information with dbGaP. If you give permission for us to share information with dbGaP now and want to end this authorization later, contact <site PI>, at (xxx) xxx-xxx. However, any data already

Attachment 16.c.

shared with dbGaP cannot be taken back. Please check your answer below. Take time to consider each option, and ask any questions you need to ask to help you understand them.

*Please initial one*

- I agree for my genetic information to be shared in a restricted manner and without identifying information with dbGaP.
- I do not want my genetic information to be shared with dbGaP.