

# Study to Explore Early Development

## Informed Consent Form

The information in this consent form is a summary of the information we previously provided to you during our phone call with you. During that call you provided verbal consent to enroll in the study.

## 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. The study is called Study to Explore Early Development (SEED). 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 with the help of schools and healthcare providers in <location>. These data are collected under the authority of Section 301 of the Public Health Service Act.

Your participation will help us understand what causes developmental problems in young children.

### 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 of autism. We know that many children have autism and other related disabilities. Autism spectrum disorders (ASD) are a set of disorders that are usually found in early childhood. There are many signs for ASD. The most common signs involve social, communication, and behavioral delays. However, we want to learn more about these children. We also want to learn more about risk factors and possible causes.

We are looking at 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.

### Who can participate?

Thousands of families across the country are being asked to be in the study. Some families were randomly chosen by birth certificate records. The names of other families were given to us by local school systems or healthcare providers.

We are enrolling families of children with and without developmental disabilities. It is important that different types of families participate. This will help us find clues about what causes children to develop differently. Children should be 2-5 years old.

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

As part of this study you will be asked to complete each of the tasks listed below. You can refuse any task and still participate in the study. The tasks include:

1. Complete a telephone interview about your health before and during your pregnancy with <child's name>
2. Complete several forms about your family's health

The telephone interview will last about 1 hour and filling out forms which will take about 2 hours. We can help you fill out the forms over the phone if you want. Even if you do not complete all parts of the study you are still considered a study participant. You are allowed to drop out of the study at any time without penalty.

### Are there any risks involved with the study?

There is little risk involved with the study. You may feel nervous answering questions during the interviews because some questions are sensitive in nature and may cause you to have negative feelings (like feeling

embarrassed). You are free to skip any questions that you do not want to answer or that make you uncomfortable. 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.

### **Why should I be in the study?**

There is no personal benefit to you for taking part in the study. Your participation will help us understand what causes developmental problems in young children. The results of the study may help us learn more about autism and other developmental disabilities. Results may also lead to better services and treatments for children with developmental disabilities.

### **Is this going to cost me anything?**

There are no costs to you associated with being in the study.

### **Will I receive anything?**

You will receive up to \$125 if you finish all the steps of the study to thank you for your participation. You do not have to wait until the end of the study to receive this. A portion of the \$125 will be given to you after each main step in the study.

### **Will the information I give be kept private?**

Your study data will be stored in a database at Michigan State University. Personally identifiable 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 in reports.

You will be given a study ID. Only staff 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). All study forms that contain your study ID or any identifying information will be kept locked in the offices of study personnel.

### **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.

### **Sharing your information with others:**

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.

### **Will I be told about the results of the study?**

We will send you a study newsletter up to two times per year. It will be mailed directly to your home or emailed to you, if you prefer. It will tell you what we are learning from the study.

**Do I have to be in the study?**

Your decision to be in the study is up to you. Your participation is voluntary. There is no penalty if you do not want to be in the study. Your child's school and healthcare services will not be affected if you decide not to be in the study. In fact, we will not discuss your decision to participate or not participate in SEED with anyone outside the study. If you decide to participate, you can drop out of the study at any time.

**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>*.