11. a.

Form Approved
OMB NO. 0920-XXXX
Exp. Date XX/XX/2020

Study to Explore Early Development

Informed Consent Form

Public reporting burden of this collection of information is estimated to average 20 minutes, 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 (0920-0010).

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. More than <*number*>families living in <*location*> will be 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 my child and I have to do to be in the study?
Families who take part in the study will be asked to do each of the tasks listed below. You can refuse any task and still participate in the study. The tasks include:

1. Complete questionnaires and interviews.
2. Allow project staff to conduct a developmental evaluation of your child.
3. Allow project staff to videotape the developmental evaluation.
4. Allow project staff to conduct a brief physical exam of your child.
5. Allow project staff to measure your head circumferences and height.
6. Allow project staff to obtain information from your child's birth record from your state Vital Statistics department.
7. Provide a saliva sample from each of the biological parents and your child.
8. Provide about 4 teaspoons of blood from you (the biological mother) and your child. The blood samples will be analyzed for biologic and genetic substances. About 3% of parents will be asked to provide an additional 4 teaspoons of blood for quality control purposes.

These activities will be collected over a series of telephone interviews that will last about 1 hour, a clinic visit that will last about 5½ hours, and filling out forms which will take about 2 hours. We can help you fill out the forms if you want before or during the visit. A detailed description of each part of the study is included in your enrollment packet. 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. We also ask whether you will let us contact you for future studies we may conduct.

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.

The developmental evaluation will take several hours and some children may become tired. Short breaks will be offered during the testing. You will receive written results from your child's developmental evaluation and you can share these results with your health care provider if you choose. You may get feedback that is unexpected and/or that indicates some developmental delays. The developmental testing results are for research only and do not substitute for a specific diagnosis or indication of treatment. Study personnel will be available to answer questions and will provide a list of local resources. But we will not be able to give a specific diagnosis.

You and your child may feel a little discomfort when having blood drawn. If you request, we can apply a numbing cream to your child's arm before inserting the needle after discussing with you. Side effects from the cream are uncommon but include temporary redness, paleness and swelling. As in every blood draw, you may get bruising at the puncture site; there is also the rare chance of later infection at the puncture site. Study staff will take every precaution when drawing blood.

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 $325 if you finish all the steps of the study to thank you for your participation and to cover out of pocket expenses such as travel. You do not have to wait until the end of the study to receive this. A portion of the $325 will be given to you after each main step in the study.

You will also receive the written results of the developmental examination of your child. We encourage you to share these with your health care provider.

We will arrange for emergency care if you are injured by this research. However, CDC and <*site*> have not set aside funds to pay for this care or to compensate you if a mishap occurs.

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.

Your biologic sample will be stored at the study lab at Johns Hopkins University. The people working on the study at the lab will enter and store your biologic sample. You can choose to store your biologic sample with or without a link to your name. Before you consent to providing biological samples, you will receive the form 'frequently asked questions about biologic samples' with more details describing storage and linking of your samples.

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.

Biological specimens
SEED is collecting and storing blood and saliva to learn if substances measured in them might be connected to autism or child development. These include genes, hormones, proteins and other substances normally found in the body as well as substances that make their way into the body. You are providing these samples to us for research purposes.

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?

You will get a letter about the results of your child's developmental evaluation. You should get this letter within 3 months of the clinic visit. The letter will explain each test your child was given. It will explain your child's scores on each test. It will tell you if your child performs at the same level as most children his/her age. It will also tell you if your child has any social, communication, or other delays. You will not receive a diagnosis. We are not giving diagnoses because the evaluation is part of a research study and is not given in order to get services or treatments. However, you may choose to share and discuss the results we provide you with your health care provider.

You may learn that your child is performing below average in certain areas. If this happens, you can speak with a study representative to get information on developmental specialists located in your area.

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.

Tests will be done on the biologic samples you give to us once enough samples have been collected. Little is known about which genes and other biologic substances are related to autism. The results from this study will only be initial clues. The same findings will have to be seen again in other studies before they can be considered useful to a particular child or family. Also, the labs that do our tests are research labs. These labs are not always approved for doing tests that are normally done for clinical care. Because of these reasons, you will not receive individual results from the biological samples that we collect for this study. We will update all participants through our website and in study newsletters in general terms about what we learn about the usefulness of these research tests. This could include results about how children develop and how genes and other biologic factors might be involved.

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*>.

We will give you a copy of this consent form to keep.

Informed Consent Statement:

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 parent Date/Time

____
Printed name (parent)

____
Printed name (Child)

Permission to Enroll MOTHER:
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)

Permission to Enroll FATHER:
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)

Other Permissions

Permission to videotape the child developmental evaluation *(please initial one)*

____ I AGREE to have my child's developmental evaluation videotaped. I understand that the tapes will be used to record certain behaviors. The tapes will also be used to make sure that the person giving the tests is doing a good job. All tapes will be stored in locked areas.

____ I DO NOT WANT my child's developmental evaluation videotaped.

Child Biological Samples

Child Saliva sample *(please initial one)*

____ I AGREE to have my child give a saliva sample.

____ I DO NOT WANT my child to give a saliva sample.

Child blood sample *(please initial one)*

____ I AGREE to have my child give a blood sample

____ I DO NOT WANT my child to give a blood sample.

Child biologic samples (saliva, blood, DNA extracted) *(please initial one)*

____ I AGREE to have my child's biologic samples stored for future research studies (WITH identifiers – you may be contacted for future studies)

____ I AGREE to have my child's biologic samples stored for future research studies (WITHOUT identifiers – you will not be contacted for future studies)

____ I DO NOT WANT my child's biologic samples stored for future research studies (samples will be destroyed after the study is over)

Parent Biological Samples

Parent saliva sample
MOTHER *(please initial one)*

____ I AGREE to give a saliva sample.

____ I DO NOT WANT to give a saliva sample.
FATHER *(please initial one)*

____ I AGREE to give a saliva sample.

____ I DO NOT WANT to give a saliva sample.

Parent blood sample
MOTHER *(please initial one)*

____ I AGREE to give a blood sample.

____ I DO NOT WANT to give a blood sample.

Parent biologic samples (saliva, blood, DNA extracted)
MOTHER *(please initial one)*

____ I AGREE to have my biologic samples stored for future research studies (WITH identifiers – you may be contacted for future studies)

____ I AGREE to have my biologic samples stored for future research studies (WITHOUT identifiers – you will not be contacted for future studies)

____ I DO NOT WANT my biologic samples stored for future research studies (samples will be destroyed after the study is over)

FATHER *(please initial one)*

____ I AGREE to have my biologic samples stored for future research studies (WITH identifiers – you may be contacted for future studies)

____ I AGREE to have my biologic samples stored for future research studies (WITHOUT identifiers – you will not be contacted for future studies)

____ I DO NOT WANT my biologic samples stored for future research studies (samples will be destroyed after the study is over)

<u>Parent biologic samples for Quality Control purposes (blood, DNA extracted)</u>

MOTHER *(please initial one)*

____ I AGREE to have additional blood drawn for quality control purposes.

____ I DO NOT WANT to have additional blood drawn for quality control purposes.

Permission to contact family for future studies

Will you allow SEED staff to contact you for future studies? If you agree, you will allow SEED staff to contact you by mail or telephone to ask your permission for you and your child to be in another study. These studies would be related to developmental disabilities. SEED staff could be from Georgia SEED or another of the SEED sites. All SEED sites are held to the same confidentiality standards and are bound by the CDC Certificate of Confidentiality. SEED sites include representatives from:

LIST SITE INSTITUTIONS

CHILD (*please initial one)*

____ I AGREE to be contacted to be asked if my child can be in future research studies.

____ I DO NOT WANT to be contacted to be asked if my child can be in future research studies.

MOTHER (*please initial one)*

____ I AGREE to be contacted to be asked if I want to be in future research studies.

____ I DO NOT WANT to be contacted to be asked if I want to be in future research studies.

FATHER (*please initial one)*

____ I AGREE to be contacted to be asked if I want to be in future research studies.

____ I DO NOT WANT to be contacted to be asked if I want to be in future research studies.

Permission to link your information in future studies
In the future, SEED researchers may want to link the information we collect about you and your child with other data sets. For example, this could be census data or data on environmental chemicals in areas where you lived. If you agree, researchers from the SEED sites listed above may link your and your child's data with other data sets. We will not contact you again or ask you to give us more information for these linkages.

CHILD *(please initial one)*

____ I AGREE to allow my child's information to be linked in future research studies.

____ I DO NOT WANT my child's information to be linked in future research studies.

MOTHER (*please initial one)*

____ I AGREE to allow my information to be linked in future research studies.

____ I DO NOT WANT my information to be linked in future research studies.

FATHER (*please initial one)*

____ I AGREE to allow my information to be linked in future research studies.

____ I DO NOT WANT my information to be linked in future research studies.

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 and your child's health, genetic and behavior 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 and your child's genetic information, and in some instances, health and behavioral 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 or your child. However, because your genetic information is unique, there is a small chance that someone could trace the information back to you or your child 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 and health information about your child 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 and your child's information with NDAR. If you give permission for us to share health 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.

CHILD *(please initial one)*

____ I agree for my child's genetic and other health information to be shared in a restricted manner and without identifying information with NDAR.

____ I do not want my child's genetic and other health information to be shared with NDAR.

MOTHER *(please initial one)*

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

____ I do not want my genetic and other health information to be shared with NDAR.

FATHER *(please initial one)*

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

____ I do not want my genetic and other health 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 and your child's information with dbGaP. If you give permission for us to share health information with dbGaP now and want to end this authorization later, contact *<site PI>*, at *(xxx) xxx-xxx*. However, any data already 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.

CHILD (*please initial one)*

___ I agree for my child's genetic and other health information to be shared in a restricted manner and without identifying information with dbGaP.

___ I do not want my genetic and other health information to be shared with dbGaP.

MOTHER (*please initial one)*

___ I agree for my genetic and other health information to be shared in a restricted manner and without identifying information with dbGaP.

___ I do not want my genetic and other health information to be shared with dbGaP.

FATHER (*please initial one)*

___ I agree for my genetic and other health information to be shared in a restricted manner and without identifying information with dbGaP.

___ I do not want my genetic and other health information to be shared with dbGaP.