

Attachment 6.b.1 – Participant Information Sheet Version 1 – participants who have biosamples from SEED 1 AND provided consent to store with identifiers

CDC and HHS Logos and/or Site Institution Logo

Study to Explore Early Development, Teen Follow-up Study SEED Teen

Rights of Research Participants

If you choose to be in this research study, you have the right to:

1. Be informed about the study and why we are doing it.
2. Have the study staff explain all study procedures.
3. Be told if there is a chance of any discomfort or risk from the study.
4. Have the study staff explain the benefits of participating in the study.
5. Ask any questions about the study.
6. Withdraw from the study at anytime without penalty.
7. Know where your information will be stored and how it will be shared.
8. Choose whether to participate in the study without the use of any force or undue influence on your decision.

Study to Explore Early Development, Teen Follow-up Study SEED Teen

Frequently Asked Questions about SEED Teen

You are invited to be in a research study being done by the Centers for Disease Control and Prevention (CDC) and the University of North Carolina at Chapel Hill (UNC). 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, Teen Follow-up Study (SEED Teen).

Your participation will help us understand health and development of children with and without autism spectrum disorder (ASD).

What is the purpose of the study?

This is a study on child health and development during the teen years. We want to better understand the health and development of teenagers with ASD, teenagers with other developmental disabilities, and teenagers from the general population. Through SEED Teen we hope to learn more about teenagers'

- Social development from early childhood to the teen years
- Health
- Health care needs
- Education needs
- Activities
- Family relationships

We also hope to learn more about parents or other primary caregivers' health and support systems.

Who can participate?

Families who previously participated in the original Study to Explore Early Development (SEED) during 2007 to 2011 are now being asked to be part of SEED Teen. We are currently contacting families from four SEED sites in Georgia, Maryland, North Carolina, and Pennsylvania.

We are only contacting those families who, at the time of their participation in the original SEED, provided consent for us to contact them to discuss future research studies such as SEED Teen.

We are enrolling families of children with and without ASD or other developmental disabilities. It is important that different types of families participate. This will help us understand the full range of health and developmental issues children face when they reach their teen years.

What will I be asked to do as part of this study?

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

Complete two questionnaires about your child:

- **The SEED Teen Health and Development Survey**
- **The Social Responsiveness Scale**

These two forms should take about an hour total to fill out. We can help you fill out the forms over the phone if you want.

Sign a consent form indicating whether or not you agree to let us contact you or your child in the future to discuss possible additional research studies.

If you choose to provide this consent you will be under no obligation to participate in any future research studies. You are only being asked to provide consent for us to contact you.

The decision about whether to provide us with consent for future contact is completely up to you. If you decide not to provide consent, it will not affect your participation in SEED Teen. Also, you will still receive \$30 as a thank you for completing the questionnaires whether or not you provide this consent.

The consent form includes a section for your child to indicate whether he or she agrees with your consent. Because your child is under 18 years of age, he/she cannot **consent** to be contacted. However, if your child is able to understand our request to contact him/her in the future, he/she can **assent** or indicate agreement to be contacted.

Sign a consent form indicating whether or not you agree to let us share some genetic information we have about you and your child with secure, national research databases investigating the links between ASD and genetics.

As you might recall, during the original SEED data collection in 2007 to 2011 we collected buccal swabs and/or blood specimens from you and your child to learn more about how genes might be connected to autism or child development. Since that time there have been several national efforts overseen by the National Institutes of Health for researchers to share their findings from their studies on genes and autism. By sharing this information, researchers hope to help speed the progress of scientific discoveries.

The decision about whether to provide us with consent for this type of genetic data sharing is completely up to you. If you decide not to provide consent, it will not affect your participation in SEED Teen or any future SEED studies. Also, you will still receive \$30 to thank you for completing the questionnaires whether or not you provide this consent.

The consent form includes a section for your child to indicate whether he or she agrees with your consent. Because your child is under 18 years of age, he/she cannot **consent** to let us share genetic information. However, if your child is able to understand our request, he/she can **assent** or indicate agreement to letting us share the information.

Are there any risks involved with the study?

There is little risk involved with the study. You may feel nervous answering some survey questions because some questions are on sensitive topics and may cause you to have negative feelings (like feeling sad or 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 better understand the health and development of teens. The results of the study may help us learn more about ASD and other developmental disabilities. Results may also lead to better services and treatments for teens 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 \$30 if you complete the two questionnaires to thank you for your participation. You will receive the full amount even if you choose to skip some questions.

Will the information I give be kept private?

Safeguards to protect your data

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 number that no one can recognize as being assigned to you. We will assign you the same study ID as in the original SEED data collection so we can combine the data you provided to us in 2007 to 2011 with the data you provide to us in SEED Teen.

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. Only staff working on the study will have access to your personal information.

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 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. 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 periodically. 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. We will not discuss your decision to participate or not participate in SEED with anyone outside the study.

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>.