

Study to Explore Early Development

Consent for Genetic Data Sharing

As you might recall, when you participated in SEED in 2007 to 2011 we collected [FILL IN: SALIVA or BLOOD AND SALIVA] from you and your child to learn more about genes. Since that time there have been several projects for researchers to share findings from studies on genes and autism. Sharing this information might speed the progress of scientific discoveries.

With your permission, we would like to share limited SEED data with two projects:

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

Both projects 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)

NDAR is an NIH database that allows researchers studying autism to share research information with each other. For more information, go to <http://ndar.nih.gov/index.html>.

Database for Genotypes and Phenotypes (dbGaP)

The dbGaP is an NIH database that has genetic data from studies of a number of conditions. For more information, go to <http://www.ncbi.nlm.nih.gov/gap>.

With your permission, SEED would like to share some of your and your child's health, genetic and behavior information (collected during our study in 2007-2011) with NDAR and dbGaP. Before sharing any data, we will remove identifying information such as your name, address, and phone number, and replace that information with a code number. Both NDAR and dbGaP are restricted. Researchers who want to use these data must apply in writing to NIH for permission. Once they are approved, researchers must follow NIH policies to access and use the data in a secure way.

Nobody will be able to know from looking at the database that any information belongs to you or your child. However, because genetic information is unique, there is a very 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 to trace genetic information are developed. This means the risk that your or your child's privacy might be breached might increase over time. **However, all researchers who access your genetic and health information have a professional obligation to protect your privacy and maintain your confidentiality.**

The decision about whether to allow us to share your data with NDAR or dbGaP is completely up to you. There will be no penalty to you if you do not give us consent. You can still be in SEED Teen and any future SEED study.

On the next pages, we ask you to choose whether or not we can share your data with NDAR or dbGaP. These consent forms will be kept in locked file cabinets. Only a few study staff will have access to your consent forms.

All responses that you give on this consent will be kept private. Any information that identifies you or your child will be used only for this project. Your information will remain confidential unless otherwise required by law. Project staff who access your information will have a legal and professional obligation to protect your privacy and maintain your confidentiality.

This Statement is provided pursuant to the Privacy Act of 1974 (5 U.S.C. § 552a):

The information you are being asked to provide is authorized to be collected under the System of Records Notices 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems. Providing this information is voluntary. The purpose of this consent is to determine whether you are willing to share some of your and your child's health, genetic, and behavior information (collected during the SEED study in 2007-2011) with NDAR and dbGaP. If you consent to share a limited amount of your and your child's data with NDAR and dbGaP, the information that you provide on this consent will be used only for that purpose. The responses that you provide on this consent will be included in a Privacy Act system of records, and will be used and may be disclosed for the purposes and routine uses described and published in the following System of Records Notice (SORN): 09-20-0136: Epidemiologic Studies and Surveillance of Disease Problems, [Federal Register: December 31, 1992 (Volume 57, Number 252)] [Notices] [Page 62812-62813].

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Informed Consent Statement: Genetic Data Sharing

National Database for Autism Research and Database for Genotypes and Phenotypes

The decision about whether to consent to sharing your genetic data is completely up to you. If you decide not to consent, there will not be any penalties.

If you give permission for us to share your genetic data with NDAR or dbGaP now and want to end this authorization later, contact [<site PI>](#), at [\(xxx\) xxx-xxx](#). However, any data already shared with NDAR or dbGaP cannot be taken back.

Please complete [Parts A, B, C, and D](#) on pages 4-5. If applicable please ask your child to complete [Part E](#) on page 6.

To be completed by MOTHER

Take time to consider each option. You may contact us at (xxx) xxx-xxx to ask any questions about this consent.

Part A

Sharing Mother's Information

Please initial all that apply

I **AGREE** to allow **my** genetic and other health information from SEED to be shared in a restricted manner and without identifying information with:

- the National Database for Autism Research (NDAR)
 the Database for Genotypes and Phenotypes (dbGaP)

OR

I **DO NOT AGREE** to allow **my** genetic and other health information from SEED to be shared with NDAR or dbGaP.

Part B

Sharing Child's Information

Please initial all that apply

I **AGREE** to allow **my child's** genetic and other health information from SEED to be shared in a restricted manner and without identifying information with:

- the National Database for Autism Research (NDAR)
 the Database for Genotypes and Phenotypes (dbGaP)

OR

I **DO NOT AGREE** to allow **my child's** genetic and other health information from SEED to be shared with NDAR or dbGaP.

Part C

Mother's signature

We would appreciate if you would sign and return this form to us for our records whether you AGREE or DO NOT AGREE to share your or your child's information.

I have read this consent form and indicated my decisions about sharing my and my child's information with NDAR or dbGAP by initialing the options above.

Printed name of mother

Signature of mother

Date/Time

If you answered **AGREE** to share your child's information with either NDAR OR dbGaP, please read the following section, **Part D**, and choose one option.

If you answered **DO NOT AGREE** to sharing your child's information, there is no need to complete the remainder of this form.

Part D

Mother's Indication of Whether Child Assent Applies (only if you indicated AGREE in Part B)

Because your child is younger than 18, he/she cannot **consent** to share genetic and other health information from SEED with NDAR or dbGaP. However, if your child is able to understand this consent form and our request, he/she can **assent** (agree) with your decision to share their information.

If your child is able to understand our request but does not provide assent, we will not share any of his/her information with NDAR or dbGaP.

Does your child have a disability or other condition that prevents him/her from understanding our request to share information? (please initial one)

Yes

No

If you answered NO, please ask your child to complete the CHILD section - **Part E** - on page 6.

If you answered YES, your consent as his/her legal guardian is all that is needed. Your child does not need to fill out **Part E**.

To be completed by CHILD (if mother answered NO in Part D)

Part E
Child Assent

Child who is younger than 18 and so cannot consent but can understand our request

Legally you cannot consent to have your information shared because you are younger than 18. However, we need to know if you want to take part in NDAR or dbGAP.

Your legal guardian gave consent for you to take part in NDAR or dbGAP. **Your initials below mean that you also agree (assent) to take part.**

Please initial all that apply

I **AGREE** to allow my genetic and other health information from SEED to be shared in a restricted manner and without identifying information with:

- the National Database for Autism Research (NDAR)
- the Database for Genotypes and Phenotypes (dbGaP)

OR

I **DO NOT AGREE** to allow my genetic and other health information from SEED to be shared with NDAR or dbGaP.

Child's signature

I have read this consent form and indicated my decisions about sharing my information with NDAR or dbGAP by initialing the options above.

Printed name

Signature

Date/Time