

## Study to Explore Early Development Consent for Genetic Data Sharing

During the original SEED study, we collected some blood and/or saliva samples from you and your child. These samples have DNA in them. We are using them to learn more about how genes might be connected to autism or child development. Since that time, there have been several national efforts for studies such as SEED to share information to help the progress of scientific discoveries.

With your permission, we would like to share limited SEED data with two of these efforts. Details about these national efforts are provided below.

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

Two national efforts for researchers to share the findings from their studies on genes and autism 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)***

NDAR is an NIH database that allows researchers studying autism to share research information with each other. It is one of several databases that make up the National Institute of Mental Health Data Archive (NDA). By sharing this information, 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/about.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, SEED would like to share some of your and your child's health, genetic and behavior information (collected during the original SEED study) with NDAR and dbGaP. We will remove identifying information such as your name, your child's name, address, and phone number, and replace that information with a code number. If you agree, the de-identified health, genetic and behavioral information will be shared with one or both of these two scientific databases maintained by the NIH. These databases are restricted and can only be accessed by approved researchers who file an application with the NIH to access the data for research purposes.

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.**

Whether or not to allow genetic and health information about you and your child to be shared with other researchers through 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. You and your child can still be in this study and any future SEED study if you decide that you do not want to share your information with NDAR or dbGaP.

We will ask you to choose whether or not we can share your and your child's data with NDAR or dbGaP below on this consent form. Consent forms will be kept in locked file cabinets. Only a few specific study staff will have access to your consent forms.

You may decide now or later that you do not want to share your and your child's information with NDAR or dbGaP. If you give permission for us to share genetic and other health information 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.

## Study to Explore Early Development

### *Informed Consent Statement: Genetic Data Sharing*

#### **National Database for Autism Research and Database for Genotypes and Phenotypes**

**The decision about whether to share your or your child's information with NDAR or dbGaP is completely up to you.** If you decide not to consent, it will not affect any benefits to which you are entitled and will not involve any penalties.

If you give permission for us to share genetic and other health information 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-E* on the following pages as they are applicable, as follows:**

**Part A.** This section is only for biological mothers of children who participated in SEED. It asks about sharing your own genetic information.

**Part B-D.** These sections are for mothers and legal guardians of children who participated in SEED. They ask about sharing your child's genetic information. If your child is an adult (age 18 years or older) and does not have a legal guardianship established, you do not need to finish section C-D. Instead, please give this form to your adult child to complete Section E.

**Part E.** This section is for your child if she or he is now over the age of 18 and is not under a legal guardianship.

## To be completed by MOTHER or Legal Guardian

Please initial the options you choose below. Take time to consider each option. You may contact us at (xxx) xxx-xxx to ask any questions about this consent.

Are you the child's biological mother?

Yes (if yes, please go to Part A)

No (if no, please skip to Part B)

## Part A (to be completed only by biological mother)

### 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.

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

\_\_\_\_\_  
Your Name (please print)

\_\_\_\_\_  
Your Signature

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

## Part B (to be completed by mother or legal guardian)

### Sharing Child's Information

1. Is your child 18 years or older?

Yes (if yes, please answer question 2)

No (if no, please skip to Part C)

2. Are you still the legal guardian of this young adult child?

Yes (if yes, please continue to **Part C** below)

No (if no, please have **your child** complete **Part E** below; you may skip part C and D)

## Part C (to be completed by mother or legal guardian)

We would appreciate if you would initial, sign and return this form to us for our records whether you AGREE or DO NOT AGREE to share your 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.

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

\_\_\_\_\_  
Printed name of child's legal guardian

\_\_\_\_\_  
Signature of child's legal guardian

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

## Part D

### Mother's or Legal Guardian's Indication of Whether Child Assent Applies (*only if you indicated AGREE in Part C*)

Because your child is under 18 years of age, or is under your legal guardianship, 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 to share information about him/her with NDAR or dbGaP, he/she can **assent** (agree) with your decision to share their genetic and health 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 YES, your consent as his/her legal guardian is all that is needed. Please return this form in the prepaid envelope.**

**If you answered NO, please ask your CHILD to complete the remaining information in this section.**

### *Child who is under 18 years of age, or under legal guardianship, and so cannot consent but can understand our request*

Although legally you cannot consent to have your information shared because you are under 18 years of age, we need to know if you want to take part in NDAR or dbGAP. The initials of your legal guardian means that he/she gives permission for you to take part. **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.

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Printed name

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Signature

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Date/Time

**Thank you for completing this form. Please have your parent or guardian return this form in the prepaid envelope.**

## Part E (to be completed by YOUNG ADULT 18 years or older)

Because you are 18 years of age or older and considered a legal adult, we need your permission to share your genetic data and other health information from SEED with NDAR or dbGaP. **Your initials below mean that you *either AGREE or DO NOT AGREE to share your information with NDAR and/or dbGaP.***

**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.

### **Young Adult'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.

\_\_\_\_\_  
Your Name (please print)

\_\_\_\_\_  
Your Signature

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

**Thank you for completing this form. Please return this form in the prepaid envelope.**