

# INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

## Protocol Title: Dissecting the Genetic Contributions to Fetal Alcohol Spectrum Disorders (DiG FASD)

### About the Study

- The purpose of the DiG FASD study is to learn how genes (genes are part of your DNA) affect the health of people who were exposed to alcohol before they were born.
- We are enrolling adults and children (including adopted people) who have Fetal Alcohol Spectrum Disorder (FASD) or who were exposed to alcohol before birth.
- We hope this study will help improve treatments and interventions for people with FASD.
- You can read more about the study at <https://digfasd.org>.

### Taking part in this study is voluntary

You will be asked to read this form and decide whether you want to participate, or if you want your child (under age 18) to participate. You may choose not to take part in the study. Your choice will not affect your benefits or relationship with Indiana University. There is no cost to you for taking part. You may receive a payment for participating in this study.

If you agree to participate, you (or your child) will be one of about 2,000 individuals taking part in this study.

### What will happen in this study and what are the risks?

#### 1. You will fill out some forms.

We will ask you to provide your (or your child's) demographic information, health and family history, and prior FASD diagnosis (if any). You may be uncomfortable answering health and medical history questions. Completing the forms will take about 20 minutes. You will have the option to complete the forms online, download the forms and return them to us, ask us to send the forms to you by mail, or complete the forms by phone or video chat.

## 2. We will confirm your information.

We will talk to you to make sure your information is correct and that you want to participate (or want your child to participate). This will take about 5 minutes.

## 3. You will take pictures of your face.

We will give you stickers to put on your (or your child's) face. Someone will take pictures of your face, and then upload them to our secure study site. This will take about 5 minutes.

## 4. You will provide a saliva (spit) sample.

We will give you a kit with instructions and a tube for you (or your child) to provide a saliva sample. You will spit into the tube, put the tube into the envelope, and put the envelope into the mail. This will take about 5 minutes. We will collect DNA from the saliva. Your DNA will tell us about the genes that you have.

If you are being seen in a clinic and the staff is already planning to draw your blood for another medical test, we will ask them to draw a little extra for the DiG FASD study instead of asking you to provide a saliva sample. You should not have an extra needle stick. There are no extra risks besides the normal risks of a blood draw.

## 5. You may receive compensation.

If you (or your child) decide to be in this study, we may compensate you for your (or your child's) time and effort with a gift card. The amount we compensate you will depend on how much of the study you complete within 90 days of consenting to participate. If you only complete the forms we will compensate you \$10. If you complete the forms and submit the photographs we will compensate you \$20. If you complete the forms, submit the photographs and submit a saliva sample we will compensate you \$50.

## **Your data might help people with FASD.**

We will examine the parts of your DNA that code all of your genes. We may use the specimens collected as a part of this study for whole genome sequencing, which involves mapping all of your DNA. This could help us understand how differences in genes explain differences in FASD outcomes and may lead to better treatments and interventions for people with FASD. As this is a research study,

you will not receive any of your (or your child's) genetic data. However, we will send you periodic updates about what we discover in the study. We may also contact you about other studies that you may want to participate in.

### **Your sample and your health information will be secured.**

We cannot guarantee absolute confidentiality, but we have processes in place to keep your data secure and will do everything we can to protect your data. This information will be kept as long as the DiG FASD study is open (or until you withdraw permission). Information from your (or your child's) DNA will be stored indefinitely at Indiana University on a secure computer. Your samples will be stored indefinitely at Indiana University in a secure room.

### **HOW YOUR INFORMATION WILL BE PROTECTED AND WHAT WILL BE SHARED**

Your saliva, DNA, pictures of your face, and health information together are your "data." The DiG FASD study gives each person a code number. The list of names and code numbers can only be seen by DiG FASD study staff. We will remove your name before sharing your data. Researchers who study your data will only see the code and not your name. Those working on research projects will not have access to the list of names and codes. There is a small risk your name could be leaked outside of the DiG FASD study. We will do everything we can to make sure this does not happen.

There is a slight risk that other information could be learned from your DNA. DNA is what you inherit from your biological parents and pass on to your biological children. Every person's DNA is unique, so there is a very small chance that someone could identify you and unique things about you based on your genetic information. However, there are rules on how people can use this information. This research follows the Genetic Information Nondiscrimination Act (GINA), a federal law which generally makes it illegal for health insurance companies, group health plans, and most employers to request the genetic information we get from this research and discriminate against you based on your genetic information. For more information about GINA, visit: <https://www.genome.gov/10002077/genetic-discrimination/>.

### **CERTIFICATE OF CONFIDENTIALITY**

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not

disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

- if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
- if you consent to the disclosure, including for your medical treatment;
- if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
- for the purpose of auditing or program evaluation by the government or funding agency.

## WHO YOUR DATA MAY BE SHARED WITH

Because the project is being done with other researchers around the world as part of the Collaborative Initiative on Fetal Alcohol Spectrum Disorders (CIFASD), data collected in this study will be sent electronically to a central location and could be used by other researchers in CIFASD. Names will not be included in these shared data. Other researchers who are not part of CIFASD may request access to these data but again, no names will be released. These other researchers will not ask for your consent to use your data in the future., Your data may be used for future research studies or shared with other researchers for future research outside of the CIFASD database. If this happens, information which could identify you (such as your name or face photograph) will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

Researchers may be from Indiana University, other universities, government agencies (like the National Institutes of Health), or private companies. Researchers may create new products (like new medicine) as part of their research. If that happens, you will not share in the profits or losses in the sale of these products.

Any published results from research on your sample will not identify you.

## OTHER ORGANIZATIONS THAT MIGHT ACCESS YOUR DATA

There are other organizations that may access DiG FASD records and your information: the IU Institutional Review Board (or its designees) and state or federal agencies with oversight responsibilities for this research, including the

Office of Human Research Protections (OHRP) and the National Institutes of Health (NIH).

Some data may also be provided to a government health research database for broad sharing with researchers around the world, but the data will not contain any information that could identify you.

After your information is shared with the people and companies listed above, the law may not require them to protect your information.

### **You can change your mind**

You may leave the study at any time. You can also decide that you want your saliva sample, photos, and information to be destroyed. If your data has already been shared with researchers (without your name), they can keep using the information but the DiG FASD study will no longer have your information to share with anyone else.

### **You can ask questions**

For questions about this study or to leave the study, contact the DiG FASD team: [fasd@iu.edu](mailto:fasd@iu.edu) or 844-378-0002. To ask about your rights as a research participant or discuss concerns, contact the IU Human Subjects Office: 800-696-2949 or [irb@iu.edu](mailto:irb@iu.edu).

**Please tell us about you:**

**Please select one:**

- I am an adult participant (I am aged 18 or older), and I am participating on my own.
- I am the parent or legal guardian of a child participant who is younger than 7.
- I am the parent or legal guardian of a child participant who is ages 7-13.
- I am the parent or legal guardian of a child participant who is ages 14-17.
- I am the legal guardian of an adult participant who is ages 18 or older.

**Participant Information:**

**Participant's First Name:**

**Participant's Last Name:**

**Parent or Legal Guardian Information:**

**Parent or legal guardian's first name:**

**Parent or legal guardian's last name:**

## **Contact Information:**

**Contact email address:**

**Contact phone number:**

**If your contact phone number is for a cell phone or mobile phone, would you like to receive text messages?**

**(If your phone plan charges you to receive text messages, you may be charged for these messages.)**

- Yes
- No

**Please tell us which cell phone provider you use so that we can send you text messages:**

- AT&T
- T-Mobile
- Verizon
- Sprint
- Virgin Mobile
- Tracfone
- Metro PCS
- Boost Mobile
- Cricket
- Other

**Contact mailing address, line 1 (street address):**

**Contact mailing address, line 2 (such as apartment number):**

**City or town:**

**State or province:**

**Zip or postal code:**

**Country:**



## Consent

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

**Signature of Participant (required for participants ages 18 and up):**

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**Signature of Parent or Legal Guardian:**

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**Today's Date:**

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**Signature of Person Obtaining Consent:**

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**Date:**

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Please return this form to:

Elizabeth Rowe  
DiG FASD Study  
Indiana University School of Medicine  
410 W. 10th Street  
HS 4015  
Indianapolis, IN 46112  
(317) 278-1100 (fax)