

Staff use only:



## **Thank you for your interest in the DiG-FASD study**



**Every person with a Fetal Alcohol Spectrum Disorder (FASD) is different**

**We think genetics plays a role**

**Help us understand FASD**

**Complete the study and receive \$60**

# 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 those 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 or your physician. 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 could take up to an hour. 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 to verify 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 a kit with instructions to take and upload pictures of your (the participant's) face to our secure study site. You will receive stickers to put on your (the participant's) face for some of these photos. This will take about 30 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 2-5 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 will complete the BRAIN-online

Researchers at San Diego State University (SDSU) have developed an online cognitive test called the BRAIN-online (Brief Assessment of Individual Neurobehavior – online version). DiG FASD has collaborated with SDSU to make the BRAIN-online part of this study. Once a saliva sample is provided, all participants 5 years and older will be invited to complete the BRAIN-online. Unfortunately, children under 5 years old are not eligible for this portion of the study.

The BRAIN-online takes 30-45 minutes and starts with a very short survey followed by online activities or games. If you agree to participate in the BRAIN-online, you will be sent a link and a unique non-identifiable code to use to access the test. You will use this code to complete the test, so SDSU will not know your name. Only DiG FASD study staff will be able to link your name with

your assigned test code. You can enroll in DiG FASD and decide not to participate in the BRAIN-online at a later time.

## 6. 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. We will compensate you \$10 for completing the forms, \$10 for submitting acceptable photographs, \$30 for providing a saliva sample, and \$10 for completing the BRAIN-online. If you complete the forms, photographs, saliva sample, and BRAIN-online you will receive a total of \$60 in compensation.

<b>Study Task</b>	<b>Amount paid</b>
Study forms completion	\$10
Photograph collection	\$10
Saliva collection	\$30
BRAIN-online	\$10
<i>All above tasks completed</i>	<i>\$60</i>

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

We may use your saliva for genomic analyses such as whole genome sequencing. Whole genome sequencing involves determining the exact order of the base pairs (chemical letters) of your DNA. Other genomic technologies continue to be developed and may be used. 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 or more parts of this study that may be available in the future.

## **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, answers to questionnaires, and information from the BRAIN-online 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 may also create a globally unique identification (GUID) number that will be assigned to your research information. This number is generated by entering some information you provide into a secure database. GUIDs can be used to connect your information to other research studies without identifying you. Any data being shared would have your name removed, so 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 may be additional risks that we cannot expect.

Data collected during the BRAIN-online will be sent electronically to a secure cloud website that is controlled by Dr. Sarah Mattson at San Diego State University. Your name will not be included in these data. When your data is sent back to us, it will be linked to the other information you provided to DiG FASD.

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. If this happens, your name will be removed before information is shared. Since your name 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).

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*We are unable to enroll children who are currently in foster care at this time.*

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*Adults eligible for this study that have a court-appointed legal guardian must be enrolled by their court-appointed legal guardian.*

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## **Please tell us about yourself:**

### **Please select one:**

- I am an adult participant (I am aged 18 or older), and I do not have a court-appointed legal guardian.
- I am the court-appointed legal guardian of an adult participant who is 18 or older.
- 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 7-13.
- I am the parent or legal guardian of a child participant who is 14-17.

## **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:**

**Question(s):**

**Do you have any questions about the information you just reviewed?**

*If you have a question, your enrollment will be suspended until a member of our study staff contacts you to answer your question(s).*

- Yes
- No

**Please enter your question(s) here:**

## **Consent**

In consideration of the information just reviewed, 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.

**Printed Name of Participant**

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

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**Printed Name of Parent or Legal Guardian:**

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**Signature of Parent or Legal Guardian:**

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**Today's Date:**

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**Printed Name of Person Obtaining Consent**

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**Signature of Person Obtaining Consent:**

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**Today's Date:**

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