Staff use only:

Thank you for your interest in the Dissecting the Genetic Contributions to Fetal Alcohol Spectrum Disorders Study (DiG FASD) Study

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 in the future.
- 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 the University of Rochester Medical Center. There is no cost to you for taking part.

If you agree to participate, you (or your child) will be one of about 2,000 individuals taking part in this study. Locally, about 100 subjects will participate.

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

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. If you have already provided this information to one of our research partners, we will utilize your previously completed forms.

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.

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.

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.

Information about your (or your child's) study participation and study results may be included in your (or your child's) electronic health record. If you have concerns about this or to obtain more detail, you should discuss this with the study team.

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 the DiG FASD study team receives your saliva sample, you 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.

Payment for participation.

If you (or your child) decide to be in this study, you will be paid for your time and effort with a gift card. The amount paid to you (or your child) will depend on how much of the study you complete. If you complete the study forms, you will receive $10. If you complete the photographs you will receive another $10. If you submit a saliva sample, you will receive an additional $30. If you complete the BRAIN-online, you will receive another $10. If you complete the forms, photographs, saliva, and the BRAIN-online you will receive a total of $60.

Study Task	**Amount paid**
Study forms completion	$10
Photograph collection	$10
Saliva collection	$30
BRAIN-online	$10
All above tasks completed	*$60*

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 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, and health information together are your "data." The DiG FASD study gives each person a code number and this list of names and assigned code numbers can only be seen by the study team. 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. 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. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance or long-term care insurance. 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.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

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. 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 the University of Rochester Medical Center and its Affiliates, Indiana University, as well as 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 Ofice 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, 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 or 844-378-0002. If you feel that you or your child's participation has resulted in any emotional or physical discomfort please contact Christie Petrenko at 585-275-2991, extension 241.

To ask about your rights as a research participant or discuss concerns, contact the Indiana University Human Subjects Office: 800-696-2949 or irb@iu.edu.

Locally you can contact the University of Rochester Research Subjects Review Board at (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will keep the information you provide, as well as your (or your child's) medical records and photographs in a secure computer system at Indiana University School of Medicine in the Department of Medical and Molecular Genetics. Sometimes, however, researchers need to share information that may identify you with

people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study, including records of external providers that are available via your electronic health record at URMC & Affiliates
- Results of medical tests

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- Indiana University
- The Collaborative Initiative on Fetal Alcohol Spectrum Disorders (CIFASD)
- National Institute on Alcohol Abuse and Alcoholism
- National Institutes of Health

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my

health information?

Then you will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research is over.

How long will this permission be valid?

This permission will last indefinitely.

May I cancel my permission to use and disclose information?

Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?

Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

No. There is a risk that your information will be given to others without your permission.

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 ages 7-13.
- □ I am the parent or legal guardian of a child participant who is ages 14-17.

Participant Information

Participant's First Name:

Participant's Last Name:

Participant's First Name at Birth:

Participant's Middle Name or Other Legal Name (if there was one) at Birth:

Participant's Last Name at Birth:

Participant's Sex at Birth:

- ☐ Male
- ☐ Female

Participant's City or Town of Birth:

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 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

_____

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

_____

Printed Name of Parent or Legal Guardian:

_____

Signature of Parent or Legal Guardian:

_____

Today's Date:

_____

Printed Name of Person Obtaining Consent

_____

Signature of Person Obtaining Consent:

_____

Today's Date:

_____