

## CDS-2024 Saliva Collection Informed Consent: Parent/Caregiver and Children

### 1. What is this study about?

The purpose of the Family Economics Study – Child Development Supplement is to understand how families, schools, and neighborhoods affect children’s and adolescents’ health and development. As part of your family’s participation, you are being asked to provide saliva samples for yourself and your children. Saliva samples contain genes, which are made up of DNA and which serve as the ‘instruction book’ for the cells that make up our bodies. We may use the saliva collected for this study for whole genome sequencing which involves mapping all of your DNA. Your DNA and survey information will allow researchers to better understand the connections between genes and measures of health and development. Taking part in the saliva collection is voluntary. There are no direct benefits to you from participating in this part of the study. The collection of saliva samples is sponsored by the National Institute of Child Health and Human Development and the Robert Wood Johnson Foundation, and is conducted by the University of Michigan. The study Director is Dr. Narayan Sastry, Research Professor at the University of Michigan’s Survey Research Center.

### 2. What is my family being asked to do?

You and your eligible children age 5 years or older are being asked to provide a saliva sample by spitting into a small container. This will be used to obtain your genomic (DNA) data. We ask you to collect the saliva yourself using a kit and then seal, package, and return the containers along with a signed and dated copy of this informed consent form. (Please keep the other copy of this form for your records.) *It will take about three (3) minutes for each person to complete this task.* We provide printed instructions to help with saliva collection.

### 3. Do I have to participate?

Your participation is voluntary. You do not have to participate and you can stop at any time. If you or your children decide not to participate, there are no penalties. You will not lose any benefits to which you would otherwise be entitled.

### 4. Are there any risks?

There are no known risks associated with completing this portion of the study. However, there are several perceived risks to providing genomic data to a repository that are related to loss of confidentiality. Below we describe our efforts to minimize any potential risk. Because everyone’s DNA is unique, it is possible that in the future someone could find out who you are just from your DNA sequence although that is not possible now.

### 5. What are the benefits?

There are no direct benefits to you or your children from participating in this study. However, the saliva that you and your children provide will help researchers learn more about factors that affect health and development. Others may hence benefit from the knowledge gained from this study.

### 6. Is everything confidential?

Your family’s confidentiality is of the highest concern to us. **The FES study will never release or share the genomic data in any way that links it to you or your children’s identity.** The saliva samples you provide will be stored at the University of Michigan without names or other identifying information, which will be stored securely and separately.

Saliva samples will be sent to a laboratory for genetic (DNA) analysis, but will be identified only by a unique number with no link to your or your children’s identity or personal information. Data from these analyses will be shared only with qualified researchers who apply for and get permission to use the data for a specific research project on any topic, such as the causes of certain health conditions or behaviors, development of new scientific methods, or where different groups of people may have come from.

NIH Public Repository – Your and your children’s genomic data will be stored in a controlled-access national database such as dbGAP, which is maintained by HID and contains similar information collected from studies around the country. NIH is a research agency that is part of the federal government. No names or other identifiers are included anywhere in this database. Data will be used for research purposes only and will not be used for profit. NIH does not allow people to try to identify individuals whose data are in an NIH-approved repository. Researches approved to access the database will agree to requirements and restrictions designed to protect your privacy and confidentiality.

When data are shared with qualified researchers, either directly or through the repository, they will be labeled with a code, instead of names or other information that could be used to directly identify you or your children. Even so, there is a

possibility that when your genomic information is combined with other information available to researchers, either now or in the future, they may be able to identify a group you belong to (like an ethnic or racial group or people with a particular disease), or less likely, you or your children personally. Summary results that combine genomic data from you and others in the study may be shared through a public national database, such as GWAS catalog, and through published scientific studies.

### **7. Are there any special protections of confidentiality?**

In addition to everything we will do to protect your family's confidentiality, this study holds a Certificate of Confidentiality from the National Institutes of Health that provides additional protection of your identity. The Certificate does not stop reporting or information-sharing that you agreed to in this consent document. We may also share your information with other researchers. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. More information about Certificates of Confidentiality and the protections they provide is available at <https://grants.nih.gov/policy/humansubjects/coc.htm>.

Another concern some people have about genetic research is that it might lead to discrimination in employment or health insurance against some groups who are found to have a higher average risk of certain health conditions. The federal Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information.

### **8. Will I be paid for participating?**

You will receive \$20 in appreciation for your participation. Each eligible child who submits a saliva sample will also receive \$20. There is no penalty if you or your children choose not to complete this component.

### **9. What if I change my mind?**

You may submit a written request to the study director to have your saliva sample or your children's samples withdrawn from the study at any time. You will be notified when the sample has been removed and destroyed. Any statistical information about your sample that has been included in the Family Economics Study – Child Development Supplement or that has been deposited in a controlled-access national database prior to your request for removal cannot be withdrawn. However, no new data will be created.

### **10. Who can answer my questions about this study?**

If you have questions or concerns about this procedure or this research, or would like to obtain more information about the study, please call our toll-free number: 1-866-796-5166.

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researchers, please contact the University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board, 2800 Plymouth Road, Building 520, Room 2144, Ann Arbor, MI 48109-2800, (734) 936-0933 or toll free, (866) 936-0933, [irbhsbs@umich.edu](mailto:irbhsbs@umich.edu). Please refer to the Family Economics Study – Child Development Supplement Saliva Collection.

**Please fill out the consent form on page 3 to provide consent for the CDS Saliva Collection.**

**Consent for Saliva Collection: Parent/Guardian and Children**

By signing below, I agree that I have read (or an interviewer has read to me) this Saliva Collection Informed Consent and I understand my rights as a study participant.

Parent/Guardian	Children
I agree to participate in my own saliva collection for the Family Economics Study – Child Development Supplement.	I agree to allow the child(ren) named below to participate in the saliva collection for the Family Economics Study – Child Development Supplement.
_____ PARENT/GUARDIAN SIGNATURE	_____ PARENT/GUARDIAN SIGNATURE for CHILD(REN)
_____ PRINT PARENT/GUARDIAN NAME	_____ PRINT PARENT/GUARDIAN NAME for CHILD(REN)
_____ DATE	_____ DATE for CHILD(REN)
	_____ PRINT CHILD'S NAME
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