KAISER FOUNDATION HOSPITALS
THE PERMANENTE MEDICAL GROUP, INC.

DIVISION OF RESEARCH

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

STUDY TITLE: Fetal and Early Postnatal Life Influences on Child Metabolic Health After Gestational Diabetes **[The SWIFT Study in Youth (SWIFT-Y)]**

Study Summary

You and your child are being invited to participate in a study conducted by researchers at the Kaiser Permanente because you are one of 1,033 women with gestational diabetes who previously participated in the Study of Women, Infant Feeding and Type 2 Diabetes after Gestational Diabetes, also known as the SWIFT Study. This new study, known as the SWIFT Study in Youth (SWIFT-Y), will include your child who was born between 2008 and 2011 when you enrolled in the SWIFT Study. We estimate the total time commitment for participation to be 3 to 3 ½ hours including one study visit and completion of online diet surveys.

The purpose of this study is to better understand how factors during early life may influence growth and health of children whose mothers developed gestational diabetes during pregnancy. A mother's blood sugar level during pregnancy is known to have lasting effects on the child's body size and future diabetes risk. Yet, much less is known about how eating habits and behaviors during early life may have lasting health benefits for these children.

We are asking your consent for you and permission for your child to participate in this study. The following is a list of activities that will happen if you agree to have your child participate.

1. You and your child will attend one study visit that will last about 2 to 3 hours to include the following:
   a) Measuring your child's blood pressure, heart rate, body weight, height, waist, body fat and skinfold thicknesses.
   b) Drawing your child's blood sample after an overnight fast, and again after drinking a sugary drink to measure sugar, fat and insulin (a hormone controlling blood sugar).
   c) Having your child fill out 6 questionnaires about his/her behaviors and health factors.
   d) Having you fill out 6 questionnaires about your child's health, behaviors and social factors.

2. Your child will complete 3 days of 24-hour recalls online about their diet with your help.

The study will involve only minimal discomfort similar to your child's usual health check-up; none or slight local pain after numbing of the skin with medication, or minor bruising associated with blood draws; and potential loss of privacy. This study will test your child's blood for diabetes and store some blood samples for future research studies.

Participation in this research study is voluntary. This study may benefit children of mothers with gestational diabetes by helping us to better understand how early life behaviors and other factors may prevent excess weight in children and type 2 diabetes.

BEFORE YOU READ THIS CONSENT FORM, YOU SHOULD HAVE READ THE KAISER PERMANENTE MEDICAL CARE PROGRAM RESEARCH PARTICIPANTS' BILL OF RIGHTS. ASK THE STUDY STAFF FOR A COPY OF THIS DOCUMENT IF YOU HAVEN'T ALREADY RECEIVED ONE.

Researchers at Kaiser Permanente in Northern California, Erica P. Gunderson, PhD, Principal Investigator (PI), and Dr. Louise Greenspan, MD, are conducting this research study. To decide whether or not you and your child want to be part of this research, you should understand the risks and benefits in order to make an informed decision. You have the right to know what the purpose of the study is, how participants are selected, what procedures will be used, what the potential risks and benefits and possible alternative treatments are, what is expected of you and your child as study participants, and to inform you of how your personal health information may be used or given to others during the study and after the study is finished. This process is called "informed consent." This consent form gives information about the research study, which the study research staff will discuss with you.

You will also be asked to sign an Authorization Form, which will describe how your personal health information may be used or disclosed by the researchers in the study.

This research study will involve participants who have the legal capacity to consent to their participation (adults) and those who do not have the legal capacity to consent to their participation (under age 18). If you are a parent or legal guardian of a child (under age 18) who may take part in this study, permission from you is required and the assent (agreement) of your child may be required. Therefore, the parent/guardian will be required to sign this form and the child will be asked to read and sign a separate assent form. We encourage you to include your child in the discussion and decision to the extent that he/she is able to understand and take part. When the word "you" appears in this consent form, it refers to you or your child depending on who is participating in the study; "we" means the researchers, nurses, and other staff.

This consent form may contain words or phrases that you do not understand. Please ask the researchers, or the study staff to explain any words or information that you do not clearly

understand. You may take home an unsigned copy of this consent form to think about or discuss the study with family or friends before making your decision. Once you are satisfied that you understand the study, you will be asked to sign and date this consent and your child will be asked to sign the assent form if you choose to have you and your child participate. You will be given a copy of the signed and dated consent form and the assent form.

Who is funding this study?
The research costs of this study are being paid by the study sponsor, The National Institutes of Health. Kaiser Permanente will be reimbursed for the time and resources used in conducting this study on behalf of the sponsor.

What is the purpose of this study?
The purpose of this study is to determine how your child's behaviors and growth during early life influence their future health, including their future risk of developing type 2 diabetes.

Why are my child and I being asked to take part in this study?
You and your child are being asked to take part in this study because you previously participated in the SWIFT Study and your child was delivered at a Kaiser Permanente (KP) hospital between 2008 to 2011 when you were enrolled in the SWIFT Study.

How many participants will take part in this study?
The 1,033 women with gestational diabetes who previously participated in the SWIFT Study after their pregnancies in 2008 to 2011 and their 1,033 children will be asked to participate in the SWIFT Study in Youth.

How long will my child and I be in this study?
If you agree that your child may participate, your child will be asked to remain in the study until she/he completes an in-person study research visit and fills out surveys online. After your child completes these study activities, we may contact you to clarify any responses, and later contact you annually to update your personal contact information for several years.

We will also collect health information from your child's electronic medical records up through the age of 17 years. If your child is not a current Kaiser Permanente member, we may contact you in the future to request copies of your child's non-KP medical records. If your child later becomes a Kaiser member, we will collect health information from your child's KP medical records. We may also contact you in the future to ask your child to participate in an extension of the SWIFT Study in Youth (SWIFT-Y) with new research questions and health outcomes.

What will happen if my child and I take part in this study?
If you agree to take part in this study and give permission for your child agree to take part in this study and sign this consent form, the following things will happen: Your child's participation will involve one in-person study visit at a Kaiser Permanente Northern California clinical facility scheduled at your convenience, and filling out 3 diet surveys online. The study visit will last about 2 to 3 hours and the following will happen at the study visit:

Study Research Activities:
Your child will prepare for the study visit on the night before by not having any food or drinks after 10 pm, and nothing to eat or drink, except water on the morning of the study visit. The study visit will include a physical exam to measure blood pressure, weight and height, waist size, and body fat. Your child will also have a blood test for diabetes by a trained research nurse (RN) or certified phlebotomist and research staff. You and your child will also be asked to fill out surveys during the study visit, and online at home. The surveys assess your child's health status, physical activity, eating habits and behaviors, body image, puberty, social factors, health history, and food situation.

In Person Study Research Visit
Before the study activities begin, we will obtain your written informed consent as the parent or guardian, and written assent from your child to participate in this study. We will update your personal contact information and ask you to provide contact information for a family member and one or more friends who will know about changes to your family's contact information in the future.

First, we will measure your child's resting blood pressure, heart rate, height and weight, and then, obtain blood samples to measure sugar, fat and insulin (a hormone that controls sugar) both before and after taking a sugary drink. Some of the blood sample from this test will be stored for future research studies and future genetic studies with your approval and your child's assent.

If your child was previously diagnosed with diabetes and is taking a medication to control his/her blood sugar, then your child should not participate in the 2-hour OGTT. We will obtain only one blood sample at fasting for this study, and your child will not take the sugary drink.

The study activities for your child's participation are described below in detail:
1) Blood Test: Your child will be asked to complete a 2-hour oral glucose tolerance test (2-Hour OGTT) or Fasting Only Test (if known diabetes). After drawing the fasting blood sample, your child will be given a sugary drink containing 1.75 grams of glucose per body weight in kg (no more than 5 Tablespoons of sugar) as a test for possible diabetes. This test involves having no food after 10 pm the night before through the start of the study visit in the morning. Then, a blood sample will be drawn, and next, your child will take a sugary drink, and another blood sample will be drawn 30 minutes later and a third sample 2 hours later. Your child will not eat or drink during the test.

A trained research nurse/phlebotomist will make your child as comfortable as possible, and collect all blood samples with needle sticks in the arm. The blood samples are to be collected as follows: the first blood sample obtained before taking the sugary drink (fasting sample); the second blood sample will be drawn at 30 minutes after the sugary drink, and the third blood sample will be drawn 2 hours after the sugary drink.

A. Amount of Blood for the 2-h OGTT Blood Test in Children with No Known Diabetes
The amount of each blood sample (at fasting, and 30 minutes and 2 hours after the sugary drink) is shown below. The overall total amount of blood for the 2-h OGTT will be about 6 teaspoons (28 cc), of which about 2 teaspoons (10 cc) will be used for research analyses, and about 4 teaspoons (18 cc) will be stored for future research and/or genetic studies upon your approval.

B. Amount of Blood for Fasting Only Test in Children with Known Diabetes:
We will obtain only a fasting blood sample of about 4 teaspoons (18 cc), of which 1 teaspoon (5 cc) will be used for research analyses, and about 3 teaspoons (13 cc) will be stored for future research and/or genetic studies upon your approval. The child will not take the sugary drink. We will measure blood sugar, fat, insulin (a hormone that controls blood sugar).

Blood Samples Time Period	**Research Analyses Amount**	**Future Research Amount**	**Overall Total Blood Amount**
Fasting	1 teaspoon	3 teaspoons	4 teaspoons
30 minutes	½ teaspoon	½ teaspoon	1 teaspoon
2-hours	½ teaspoon	½ teaspoon	1 teaspoon
Total	**2 teaspoons**	**4 teaspoons**	**6 teaspoons**

The blood test results will indicate whether your child has a normal response to sugar intake, prediabetes, or diabetes. The total amount of blood poses no more than minimal risk to children between the ages of 9 to 14 years. The blood collection for future research studies is optional and you will be asked for your permission for use of your child's blood for future research studies in the next sections.

Research Test Results: We will mail the Fasting Only or 2-h OGTT blood test results to you about 2 to 3 months after your child's study visit. If you have questions about any of your child's test results, we recommend that you contact your child's health care provider and share a copy of your child's study test results with the provider for medical advice. If the results show that your child has blood sugar elevation(s) consistent with diabetes, then you should consult with your child's health care provider for medical advice and to confirm the test results.

2) Physical Measurements. Trained research staff will measure your child's:
- Blood pressure in a seated position by putting a cuff on your child's right arm, and having a digital machine take 3 readings of blood pressure, a minute apart each time.
- Heart rate by a digital machine during the blood pressure measurement.
- Weight by having your child stand on a digital scale (wearing light clothing without shoes).
- Height by having your child stand up straight against a wall (without shoes).
- Waist size with a measuring tape placed around your child's waist (directly on the skin).
- Body fat by measuring four skinfold thicknesses, with research calipers that measure the thickness of the fat in the arm, upper back, hip and belly regions.

- Body fat by using Bioelectrical Impedance Analysis (BIA): This test involves lying on a flat surface for about two minutes while two electrodes (sticky pads with a wire attached to them) are attached to your child's foot and hand. The measure involves a very small electrical current that is passed through the body and a reading is taken which, along with your child's height and weight, is used to calculate your child's body fat. This very small electrical current cannot be felt. This test has been done for many years in very young and older children.

3) Surveys on Child Health Status, History, Lifestyle and Behaviors, and Household:
There are 6 surveys for the parent and 6 surveys for the child that may be completed at the study visit and/or at home using an online secure account. We will ask you to complete surveys about your child's health status, medical history, use of medical services, medicines your child may have used recently, your medical insurance, family health history, your household and social factors, food situation and your child's behaviors. We will also ask you to help your child complete surveys about his/her usual dietary intake and food habits, screen time, stress, physical activity, and lifestyle behaviors. Your child will also be asked fill out surveys about lifestyle habits, self-report of pubertal stage, and their body image (on their own). Research staff will also administer a survey interview about your child's sleep habits. The total time to complete all surveys at the study visit is 1 hour each for the parent and the child.

4) Report of Visit Results: We will provide you with a report of your child's blood pressure, weight, and height at the study visit. For blood pressures above normal levels, we will advise you to contact your health care provider.

Complete Online Surveys: Your Child's Usual Dietary Intake:

You be asked to help your child to fill out standardized self-administered surveys online. We will provide you with your child's unique ID and a secure link via email or the study website to complete the online surveys at home. The ASA24 survey will ask your child to report his/her usual 24-hour diet intake on three separate days; including two weekdays, and one weekend day using the online 24-hour dietary site (ASA24). The survey asks your child to recall his/her dietary intake during the previous day covering a 24-hour period. The study staff will assist you and your child in filling out one or more of the three days for the 24-hour dietary recall. After completing each day's recall taking about 15 to 20 minutes, you may choose to receive a summary report of your child's nutrient intake through the website. The total time for the online dietary intake recall surveys is 45 minutes to 1 hour.

Study Contacts

Before and/or after your child's study visit, you will receive a telephone or video conference reminder call (5-10 minutes) from the research staff to assist with completion of the ASA24

(online automated self-administered 24-hour dietary recalls). Reminders may also be sent by email, telephone calls, voicemail, postcards, and/or phone text messages. You may specify your preferences for the method, the time of day and day of the week to receive the messages.

Research staff may contact you at other times during the year to invite you or your child to join future research studies as per your consent in the original SWIFT Study, and SWIFT Study in Youth. In the future, you may also receive additional forms to update your contact information and to update you and your child's health outcomes by mail to complete and return.

The SWIFT Study, SWIFT Study in Youth (SWIFT-Y) and KP Electronic Medical Records Data

This study will include analyses of research data already collected at the original SWIFT Study visits, and ongoing health status data from the KP electronic medical records for you and your child. These data include your clinical pregnancy history, course and outcomes, newborn outcomes, growth and health of your child, vital signs, lifestyle behaviors, medical conditions and diagnoses, health history for you, your child and other family members, social factors, laboratory tests, medications, medical conditions, diagnoses, hospitalizations, and lifestyle factors. We also will include analyses of stored blood samples and research data collected from your previous SWIFT study visits, telephone interviews, and postcard mailings about you and your child's health information.

Will the information collected be used in future research?

The data collected from this study may be used for future research studies or distributed to another investigator for future research. Information that identifies you and your child will be removed from the data.

If you approve, your child's blood sample will be stored indefinitely for possible future research studies. However, prior to any future research studies of genetics we will ask for your or your child's permission if they are 18 years of age or older at that time.

What are my responsibilities while I am in this study?

As parent or guardian of the child participant in this study, the expectations are as listed below:

- You will attend the research visit with your child.
- You will fill out surveys and assist your child in filling out surveys at the visit or online.

What are the potential risks, side effects and discomforts of being in this study?

The risks associated with this study include those related to physical measurements, blood draws, and potential loss of and confidentiality of your health information.

Blood pressure will be measured in a seated position and there may be minor discomfort from the cuff tightening around the upper arm.

Skinfold measurements involve uncovering of the mid-section, arm and upper back areas of skin for waist circumference and skinfold thicknesses will be conducted in a private room. The measurements of skinfold thicknesses involve slight pinching of fat tissue in the areas of the upper arm, under the shoulder blade, and abdominal area above the hip bone. This may lead to a slight, brief discomfort.

Body composition measures include body fat, water and muscle mass using the machine with a very small electrical current that is non-invasive and harmless. This procedure is painless and has been used in many studies of adults, pregnant women and young children. The sticky pads may leave a small residue which is easily washed off with water.

Surveys: Study surveys may include questions that may seem very sensitive and personal. You and your child may refuse to answer any of the questions that either of you do not wish to answer.

Other Risks:

Oral glucose tolerance test: For the oral glucose tolerance test, there may be minor discomfort related to the fasting period including hunger and headache, as well as some inconvenience. An additional minor side effect from the 2-hour OGTT may be nausea from taking the sugary drink, but this is usually not serious, and very brief.

Risks related to drawing blood

Very minor local pain from needle, slight skin bruising, and in rare instances, an infection might occur at the site where blood is drawn. There is also the possibility of dizziness or fainting while your child's blood is being drawn.

Risks related to genetic research

This research study involves collection of blood samples for future genetic testing per your approval. You are free to refuse to allow storage of extra blood for future genetic studies. It is your choice. While this study has safeguards in place to protect your confidential genetic information and to make it extremely unlikely that your child's identity would be connected with any special studies that are performed on these biospecimens, it is possible that this information could be discovered by someone who is unauthorized to have access to it.

A federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for employers, health insurers and group health plans to discriminate against you based on your genetic information. GINA limits the way these parties can use genetic information. Be aware that GINA does not protect you or your child against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

If you agree to take part in genetic testing, the genetic information we collect or obtain through this research will not affect you or your child's eligibility for future medical care, membership in Kaiser Foundation Health Plan, or the cost of your premiums or benefits. In California, state law (CalGINA) requires that employers with 5 or more employees may not use your genetic information, obtained from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. Be aware that these laws **do not** protect persons against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Privacy Risks

There is a small chance that being in this study may involve a loss of privacy. State and federal laws require Kaiser Permanente to keep your health information private and safe. In this study, your information may be shared with researchers outside of Kaiser Permanente including possibly outside the United States. Although Kaiser Permanente requires these outside researchers to keep your information private and safe, the laws that protect your information may not apply. Therefore, Kaiser Permanente cannot guarantee that your information will be protected once it is sent outside of Kaiser Permanente.

Are there any benefits to being in this study?

Taking part in this research study may not benefit your child personally, but we may learn new things that will help others. It is possible that your child may benefit from early detection of health problems, if present. It is hoped that the information gained from the study will help in early prevention of type 2 diabetes among children of mothers with gestational diabetes.

What are my choices if I do not want my child to be in this study?

This study is not designed to diagnose, treat or prevent any disease. The study will examine the relationship of gestational diabetes to your child's future health. Your alternative is not to have your child participate in this research study. Your child's regular doctor will be able to give you information about prevention and treatment of diabetes.

Will there be any costs to me to take part in this study?

There will be no cost to you for participating in the study. We will waive any blood test costs (no co-payment for the blood tests). Treatment for any conditions discovered during this testing will not be covered by the study. This study does not cover the cost of follow-up care that might be related to the study tests. Such care (if needed) shall be covered by you or your insurance company.

If you and your child are a Kaiser Foundation Health Plan member, all aspects of your standard medical care will continue to be provided to you and your child according to the terms of your plan benefits described in your applicable plan Evidence of Coverage or Summary Plan Description, which may include copayments, coinsurance, and deductibles.

Will I be paid for my child to take part in this study?
If you agree to have your child participate in this study, you will be compensated in the total amount of $150 upon completion of all study activities. Participants will receive compensation for attending the in-person study visit by receiving a gift card of their choice to Amazon or Target in the amount of $100 to reimburse your time. When your child has completed the online dietary surveys for 3 days of 24-hour recalls (ASA24), you will receive a $15 gift card, and when he/she has completed all other study surveys, you will receive a second $15 gift card (both of your choice to Amazon or Target) at the study visit, or by mail within 2 weeks after the date of completion of the surveys. You will receive a third $20 gift card after you fill out the parent/guardian surveys. We will provide parking and ride vouchers, if needed.

The biospecimen samples will be used only for research and will not be sold or used directly for commercial products. Even though research done with the samples may be used to help develop new products or diagnostic tests that could have commercial value in the future, if a commercial product is created from this research, you will not receive any payment from such a product and you will not own such a product.

What will happen if my child or I are injured during the study?
If you or your child is injured during your participation in this study, you should tell the study personnel at the study visit or contact study staff at the telephone number listed in this consent form. Medical care may be obtained in the same way you would ordinarily obtain other medical treatment.

Further information regarding medical treatment for research-related injuries can be obtained from the study doctor or other authorized personnel.

Any injury or condition experienced by a member of KFHP, as a result of being in this study, will be treated and covered as described in your Evidence of Coverage or Summary Plan Description.

No free medical care or other form of compensation will be offered by Kaiser Foundation Health Plan, Kaiser Foundation Hospitals, The Permanente Medical Group, Inc., or the Kaiser Permanente staff conducting the study.

Your consent to and your permission to allow your child to participate in this research study does not take away any legal rights, which you or your child may have in the case of negligence or legal fault of anyone who is involved with this study.

It is not the policy of the U.S. Department of Health and Human Services, or any federal agency funding the research project in which you are participating, to compensate or provide medical treatment for study participants in the event the research results in physical injury.

Will my and my child's information be kept confidential?
Every effort will be made to maintain your privacy and your child's privacy. However, you and your child's personal information may be disclosed if required by law. As a participant in The SWIFT Study in Youth, you and your child have been given a unique study identification number. This same study number will be used to record you and your child's study information. No personal identifiers will be linked to you and your child's study data. However, some personal identifiers (your name, your child's name, telephone number, and address) will be used to schedule your child's study visit appointment and to mail study letters.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Under California law, the researchers must report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, he or she may be required to report such information to the appropriate authorities.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document, study survey and research measurements, laboratory research results, stored biospecimens and research data from the medical record data.

To the extent permitted by law and by signing this consent form, you allow access for the following representatives to inspect your and your child's research and clinical records without removal of identifying information, such as your name, initials, date of birth, sex, and race, to make sure that the information is correct and to evaluate the conduct of the study.

- Authorized representatives of the Sponsor, the US Department of Health and Human Services (DHHS), the National Institutes of Health (NIH), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- Government agencies; The U.S. Food and Drug Administration (FDA); the Department of Health and Human Services (DHHS); or other governmental regulatory agencies [in the US and other countries] involved in keeping research safe for people;
- Kaiser Permanente Northern California Institutional Review Board (a formal committee that reviews research studies to protect the rights and welfare of participants)
- Representatives of Kaiser Permanente
- Kaiser Foundation Research Institute and others at Kaiser Permanente responsible for monitoring research

Because of the need to allow access to your and your child's information to these parties, absolute confidentiality cannot be guaranteed. All study records will identify you through a code number. The study investigator will ensure that the link between your name and these code numbers will never be released outside the study site. All coded records will be kept confidential and stored in a secure area.

Your identity will not be revealed in any publication or release of study results.
If your child is a current Kaiser Permanente member, by signing this consent form, you will also be giving consent for the medical research investigator or his/her assistants to review your child's medical records as may be necessary for this study.

Can I choose to not participate or withdraw from the study?
Participation in this study is completely voluntary. You are free to refuse to participate in this study. Your decision whether or not to participate in the study will not affect you or your child's medical care. If you decide to participate, you are free to change your mind and discontinue participation at any time without any effect on your or your child's medical care or eligibility for future care or membership in KFHP.

Will I receive results from the *[Fasting Test, 2-hour OGTT]* for my child in this study?
We will provide you with the results of your child's blood test for diabetes. We will not disclose any of the research tests to your child's healthcare provider.

What if I have any questions or problems?
In case of study-related questions, problems or injuries, you can call the investigator responsible for the study within Kaiser Permanente in Northern California [Erica P. Gunderson], Ph.D., M.P.H., Principal Investigator at *[415-418-0234]*, or the SWIFT Study team at the toll-free phone number, 1-866-279-8624 or email at: swiftresearch@kp.org.

Questions about your rights as a study participant, comments or complaints about the study may be presented to the Kaiser Permanente Northern California Institutional Review Board 1800 Harrison Street, Oakland. CA 94612, or 1-866-241-0690.

Permission to Use Your Child's Blood Samples for Future Research Studies.

You may give your permission to store additional blood for two types of future research studies. First, we ask your permission to store your child's blood sample for use in future research studies that **do not** involve genetic testing (**exclude genetics)**. Next, we ask your permission to store your child's blood for use in future research studies of **Genetics**.

1. Optional Blood Collection for future research studies (Excludes Genetic Studies).

_____ (initials) I agree for my child to have additional blood collection for **future research** studies that **exclude genetics**.

_____ (initials) I do not wish to have my child to take part in additional blood collection for **future research** studies that **exclude genetics**.

2. Optional Blood Collection for future studies of Genetics

_____ (initials) I agree for my child to have additional blood collection for **future studies of Genetics**.

_____ (initials) I do not wish for my child to take part in the additional blood collection for **future research studies of Genetics**.

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CONSENT TO BE IN THE STUDY:
I have read (or someone has read to me) the above and am satisfied with my understanding of the study, its possible benefits, risks and alternatives. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I will be given a copy of this consent form, and the Authorization To Use and Disclose Protected Health Information.

Please also see the attached "Research Participants' Bill of Rights".

BY SIGNING BELOW, I WILLINGLY AGREE TO HAVE MY CHILD AND ME PARTICIPATE IN THE RESEARCH STUDY AS DESCRIBED IN THIS FORM.

_____ _____
Parent/Guardian's Signature Date

_____ _____
Parent/Guardian's Name Printed Child's Name Printed

Legally Authorized Representative (if applicable):

_____ _____
Legally Authorized Representative's Signature Date

_____
Legally Authorized Representative's Printed Name

_____
Legally Authorized Representative's Relation to Participant

RELATIONSHIP TO PARTICIPANT:

☐ Participant's Agent as designated by an advance health care directive.
☐ Conservator Guardian of participant with authority to make health care decisions for the participant.
☐ Spouse of participant
☐ Domestic partner of participant
☐ Adult son or daughter of participant
☐ Custodial parent of participant
☐ Adult brother or sister of participant
☐ Adult grandchild of participant
☐ Available adult relative (indicate degree of kinship:_____)

I certify that I have explained to the above individual the nature and purpose, the potential benefits and possible risks associated with participation in this clinical research study. I have answered any questions that have been raised and have witnessed the above signatures.

Printed Name of Person Explaining Consent

Signature of Person Explaining Consent | Date

INTERPRETER STATEMENT:
I have interpreted this consent form into a language understandable to the participant and the participant has agreed to participate as indicated by their signature above.

Printed Name of Interpreter

Signature of Interpreter | Date