KAISER FOUNDATION HOSPITALS
THE PERMANENTE MEDICAL GROUP, INC.

Division of Research at Northern California

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

STUDY TITLE: Metabolite Profiles Preceding Progression to Diabetes Mellitus After Gestational Diabetes. **[SWIFT Women 10-Year Follow Up]**

Study Summary

You are being invited to participate in a study conducted by researchers at Kaiser Permanente because you are one of 1,033 women diagnosed with gestational diabetes from 2008 to 2011 who previously consented to participate in the Study of Women, Infant Feeding and Type 2 Diabetes after gestational diabetes, known as the SWIFT Study. The new study is called the SWIFT Women 10-Year Follow Up Study (SWIFT Women 10-Y), and will involve one research visit that will last about 2 to 3 hours, and your filling out surveys online.

The purpose of this study is to develop a simple blood test to predict future risk of developing type 2 diabetes up to 10 years or more after gestational diabetes pregnancy. We identified metabolites at 6 to 9 weeks after the SWIFT pregnancy that improved prediction of the woman developing overt diabetes up to two years after delivery. The SWIFT 10-Year Study will expand this simple test to predict diabetes status 10 years or more before its onset. This test will help women by providing specific information about the future risk of developing diabetes.

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

1. You will attend one study visit that will last about 2 to 3 hours to include the following:
   a) Measuring your blood pressure, heart rate, body weight, height, waist, and body fat.
   b) Drawing your blood sample after an overnight fast, and again 2 hours after drinking a sugary drink to measure sugar, fat and insulin (a hormone controlling blood sugar), and biomarkers related to heart health.
   c) Filling out questionnaires about your lifestyle behaviors, health history, pregnancy history, your child and family's health history, medication use, and social factors.
2. Completing surveys online for 3 days of 24-hour recalls about your dietary habits.
3. Filling out questionnaires about your health and other factors at another time.

The study will involve only minimal discomfort similar to your usual health check-up; none or slight local pain, or minor bruising associated with blood draws; and potential loss of privacy. This study will test your blood sample for diabetes and heart disease markers, and also store

some blood samples for future research studies. Participation in this study is voluntary. This study may benefit women with gestational diabetes by helping us to develop less burdensome tests for early prediction of diabetes and newer approaches for type 2 diabetes prevention.

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 and Dr. Mara Greenberg, MD, co-investigator, are conducting this research study. To decide whether or not you 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 as a study participant, and to inform you of how your personal health information may be used or given to others during the study and after 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 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 if you choose to participate. You will be given a copy of the signed and dated consent form.

Who is funding this study?
The research costs of this study are being paid by the study sponsor, The National Institutes of Health.

What is the purpose of this study?
The purpose of this study is to develop a simpler and more convenient test for early prediction of the risk of developing type 2 diabetes up to 10 years after the delivery of a pregnancy with gestational diabetes. The new test may be used to improve diabetes prevention by developing new treatments and approaches.

Why am I being asked to take part in this study?
Because you previously participated in the original SWIFT Study, you are being asked to participate in the SWIFT Women 10-Year Follow Up Study.

How many participants will take part in this study?
All women who previously participated in the SWIFT Study (n=1,033 women with gestational diabetes delivered in 2008-2011) will be asked to participate in this study.

How long will I be in this study?
If you agree to participate in this new study, you will be asked to remain in the study until you complete an in-person study visit. If you are a current Kaiser Permanente (KP) member, we will ask for your permission to collect health information about you through review of your electronic medical records. We will follow your health status after your study visit via KP members' electronic medical records. If you are not currently a KP member, we may contact you in the future to request copies of your non-KP medical records. If you become a KP member again in the future, we will review your KP medical records.

After you complete the study visit and online surveys, we may contact you by phone or e-mail to clarify any responses, and again annually, to update your contact information. We may also contact you again in the future to ask you to participate in another extension of the SWIFT Study with new research questions and health outcomes.

What will happen if I take part in this study?
Your participation in this research study will involve an in-person study visit lasting about 2 to 3 hours at a Kaiser Permanente Northern California clinical facility at your convenience.

If you agree to take part in this study the following procedures will happen at the study visit:

In Person Research Visit
First, we will obtain your written informed consent to participate in the study. We will ask you to update your contact information and provide the contact information of a family member and one or more friends who will know about any changes to your contact information in the future.

Trained research staff will measure your blood pressure, heart rate, weight, height, waist size, and body fat. A certified phlebotomist will draw the blood sample(s) from a vein in your arm.

Women without known diabetes will be administered the 2-hour 75 g oral glucose tolerance test (2-hour 75 g OGTT). This test will involve drawing a fasting blood sample, after which you will consume a sugary drink and then wait 2 hours to have a second blood sample drawn.
Women who have diabetes will have only the fasting blood sample drawn.

There will be no co-pay charge for the blood tests. Some of the blood sample will be used to measure glucose, insulin and HbA1c, biomarkers for heart health and other disease risk, and some will be stored for future research studies and future genetic studies per your approval.
You will also be asked to fill out questionnaires about your lifestyle and health behaviors, health history, your child and family's health history, and social factors.

Below are the study activities described in detail:

1) Research Blood Draw
Research staff will make you as comfortable as possible for the appropriate blood test. Women without known diabetes will undergo the 2-hour 75 gram oral glucose tolerance test (OGTT). Women with overt diabetes will undergo the Fasting Blood Test Only. The blood sample(s) will be drawn from the vein in your arm. The fasting blood sample will be obtained after an overnight fast of 10 hours or more, and will be used to measure blood sugar, insulin, HbA1c, and biomarkers of heart disease and metabolism, and to store blood for future research studies.

If you currently have diabetes and take medication to control your blood sugar, you should not participate in the 2-hour oral glucose tolerance test (2-h OGTT). The 2-h 75 g OGTT involves drinking a high-sugar drink, not taking any food or beverages for two hours, and having a second blood draw. The 2-h OGTT is a test for possible diabetes, and the same test you had at all previous SWIFT Study visits. Blood drawn at 2 hours after consuming a sugary drink (glucola beverage) will be used to measure blood sugar, insulin, and biomarkers, and to store blood for future studies.

After your blood test is completed you will receive something to eat and drink. The blood test results will indicate if you have diabetes, prediabetes, or a normal response to sugar intake, or diabetes control.

Amount of blood collection for: 1) 2-hr 75 g OGTT Test (No Known Diabetes), and 2) Fasting Only Test (Diabetes). You will only do one of the two tests mentioned.

Participants without Known Diabetes: 2-hr 75 g OGTT Test
For KP members, the total amount of blood drawn will be about 4 ½ Tablespoons (66 cc), which includes 4 teaspoons (20 cc) for KP clinical tests (10 cc at fasting and 10 cc at 2 hours), about 4 teaspoons (22 cc) for study analyses, and about 5 teaspoons (24 cc) to be stored for future research studies and future genetic studies upon your approval.

For non-KP members, the total amount of blood drawn will be about 3 Tablespoons (46 cc) which includes about 4 teaspoons (22 cc) for study analyses, and about 5 teaspoons (24 cc) to be stored for future research studies and future genetic studies upon your approval.

Participants with Overt Diabetes: Fasting Only Test
For KP members, the total amount of blood drawn will be about 3 Tablespoons (46 cc), including 2 teaspoons (10 cc) for KP clinical tests, about 4 teaspoons (18 cc) for study analyses, and about 4 teaspoons (18 cc) to be stored for future research studies and future genetic studies upon your approval.

For non-KP members, the total amount of fasting blood drawn will be about 2 ½ Tablespoons (36 cc), including about 4 teaspoons (18 cc) for study analyses and about 4 teaspoons (18 cc) to be stored for future research studies and future genetic studies upon your approval.

Type of Test	**Total Amount of Blood Sample**	**Amount of Blood for Analyses**		
		KP HealthConnect Clinical Tests	Study Analyses	Biobank for Future Research Studies
Fasting + 2-h 75g OGTT				
KP-Member	66 cc (4 ½ Tbsp)	20 cc	22 cc	24 cc
Non-KP member	46 cc (3 Tbsp)	-----	22 cc	24 cc
Fasting Test Only				
KP-Member	46 cc (3 Tbsp)	10 cc	18 cc	18 cc
Non-KP member	36 cc (2 ½ Tbsp)	-----	18 cc	18 cc

The amount of blood drawn for the study in KP members is larger than for non-KP members because this additional blood will be used for the KP clinical test results that will become part of your KP medical record.

Test Results: We will send you a letter with the results of your blood sugar tests within 2 to 4 months after your study visit. However, please remember that for current Kaiser members, your blood sugar test results will be posted in your Kaiser Permanente medical record as soon as they become available (within 1 to 2 days). Your physician will be able to view the KP laboratory results. You may also access your test results via the KaiserPermanente.org website to view your electronic medical record. For KP members with any elevated blood test results, your results will be forwarded to your Primary Care Physician (PCP) for follow up. For non-KP members, if you have any elevated blood test results, or have questions about any of your laboratory test results, we recommend that you contact your health care provider and share a copy of your study test results.

If the results of your fasting, 2-hr oral glucose tolerance test, and/or HbA1c tests show that you have elevations consistent with diabetes, then you will be contacted again by the SWIFT study staff and asked to return for a one time repeat testing within the next 2 to 6 months with our study team (following the same procedures above) to confirm the test results.

2) Body Measurements:

At the Study Visit, the research staff will measure your:

- Blood pressure in a seated position by putting a cuff on your right arm, and having a digital machine take 3 readings of blood pressure, a minute apart each time.
- Heart rate will be measured by a digital machine during the blood pressure measurement.
- Weight by having you stand on a digital scale (wearing light clothing and without shoes).
- Height by having you stand up straight against a wall (without shoes).
- Waist size measured with a measuring tape placed around your waist (directly on the skin).

- Body fat 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 foot and hand. The procedure is painless and has been used in many studies. The measure involves a very low frequency electrical current that is passed through your body and a reading is taken which is stored in a computer, along with your height and weight, to calculate your body fat, water, and muscle mass content.

3) Health History, Pregnancy, Social Factors, Family Health, and Lifestyle Behaviors:

We will ask you to complete surveys about your current health and medical history related to medical events and use of medical services, and the medicines you have used recently. The surveys will also ask about your family's medical history, family size and ages of children, the SWIFT child's health, your pregnancies, your employment, income and occupation, social factors, socio-demographics and other factors related to your everyday life such as depression, sleep habits and disorders, usual dietary intake, physical activity, smoking habits, alcohol intake, and other health behaviors. We will also ask about your pregnancy course and outcomes, and reproductive health history. For your pregnancy with gestational diabetes delivered when you first joined the SWIFT Study, we will ask you about your child's health and medical events, and your additional pregnancies and outcomes. In addition, you may be contacted in the future to participate in other SWIFT Study-related activities and other new studies.

Data from SWIFT Study Visits and KP Electronic Medical Records

The analyses for this study will include data obtained from KP electronic medical records, and data collected at all SWIFT Study visits including the clinical and metabolic risk factors, biochemical markers, lifestyle behaviors, pregnancy history and outcomes, reproductive health factors, your child's infant health outcomes, medical conditions and diagnoses, medications, hospitalizations, yours and your family's medical history, and health outcomes, including blood pressure, physical vital signs, behaviors, and body fat levels, as well as biochemical markers and measures in stored blood samples from your previous SWIFT study visits per your signed informed consent, telephone interviews, and mailings as well as your KP medical record.

Complete an Online Survey to Report Usual Dietary Intake:

We will ask you to fill out a standardized automated self-administered dietary survey available from the NIH, an online website created for research study participants. We will send your unique ID and a secure link via email. The study staff will assist you in filling out one of the three days for the 24-hour dietary recall during the study visit. The 3-day 24-hour dietary survey (ASA24) will ask you to recall your dietary intake during the previous day covering a 24-hour period, most commonly, from midnight to midnight on the previous day. This survey will involve your reporting of your usual 24-hour diet intake on three separate days; including two weekdays, and one weekend day. After the study visit, you will complete the two days of the

ASA24 using the online website account. After completion of the 3 days of diet recall surveys, you will receive a summary evaluation of your nutrient intake through the website online.

Study Contacts

After your study visit, you will be contacted by the research staff to check your contact information, and the completion of the ASA24 dietary recall or other surveys. Reminders may also be sent by email, phone voicemail, video calls, postcards, and/or phone text messages. You may specify your preferences for the time of day, and day of the week to receive messages, as well as the method of staff sending you the reminders (e-mail, text, or voicemail).

The reminder telephone calls will take about 5-15 minutes. Research study staff may call you at other times during the year to invite you to join future research studies as per your consent in the original SWIFT Study. In the future, you may also receive additional forms to update your contact information and to update your health outcomes by mail to complete and return.

The SWIFT Women 10-Year Follow Up and KP Electronic Medical Records

This study will include analyses of research data already collected at the original SWIFT Study visits, and health data from the KP electronic medical records for you and your child. These data include your clinical pregnancy history, course and outcomes, vital signs, lifestyle behaviors, medical conditions and diagnoses, health history for you, your family and your child, birth and infant health, social factors, laboratory tests, medications, medical conditions, behaviors, hospitalizations, social, 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 mailings about you and your child's health information.

<u>Optional specimen collection Stored for Future Research Studies</u> (NOT Genetic research).

_____ (initials) I agree to have additional blood collection for **future research** studies.

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

<u>Optional specimen collection Stored for Future Genetic Studies</u>.

_____ (initials) I agree to have additional blood collection for **future genetic** research studies.

_____ (initials) I do not wish to take part in the optional additional blood collection for **future genetic** research studies.

Will the information collected be used in future research?

If you approve, your stored blood sample and research data may be given to other researchers in the future for research studies. These blood samples will be stored indefinitely and may be used and shared in the future for research, and/or genetic research as you have indicated by your approval above. The blood samples provided by you will be analyzed in the laboratory to determine metabolites, biomarkers and clinical measures that may include, but are not limited to the development of diabetes, heart disease or other diseases.

Information that identifies you will be removed from the data or specimens collected in this research and used for future research or distributed to another investigator for future research without your consent. Stored blood samples will be connected to your study information only by a unique study number, which was given to you when you began participating in the study. Your name and other personal information will **not** be linked to your blood samples.

What are my responsibilities while I am in this study?

As a participant in this study, the expectations are as listed below:

- You will attend the research visit.
- You will fill out surveys at the visit and/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 the 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.
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 may refuse to answer any of the questions that 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 lessened by numbing the 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 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 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 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 would collect or obtain through this research will not affect your 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?

It is possible that you may benefit from early detection of health problems, if present. You will also have the satisfaction of being in a research study that may help others lead to earlier prediction of future risk of developing type 2 diabetes for women with gestational diabetes. It is hoped that the information gained from the study will help in early prevention of type 2 diabetes among women with gestational diabetes.

What are my choices if I do not want 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 future health. Your alternative is not to participate in this research study. Your 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.

For Kaiser Foundation Health Plan members, all aspects of your standard medical care will continue to be provided to you 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 to take part in this study?

If you agree to participate in this study, you will be compensated in the 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 you have completed the online dietary surveys for 3 days of 24-hour recalls (ASA24), you will receive a $25 gift card, and when you have completed the other online study surveys, you will receive a second $25 gift card (both of your choice to Amazon or Target) at the study visit, or within 2 weeks after the date of completion of the surveys. We will provide parking and ride vouchers, if needed.

If you are a KP member, all aspects of your standard medical care will continue to be provided to you 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.

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 I am injured during the study?
If you are 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.

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 information be kept confidential?

Every effort will be made to maintain your privacy. However, your personal information may be disclosed if required by law. As a participant in the SWIFT Women 10-Year Follow Up Study, you have been given a unique study identification number. This same study number will be used to record your study information. No personal identifiers will be linked to your study data. However, some personal identifiers (your name, telephone number, and address) will be used to schedule your study visit appointment and to mail study letters. 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), and the Kaiser Permanente Northern California Institutional Review Board (IRB) (a formal committee that reviews research studies to protect the rights and welfare of participants), may have access to and copy medical records and records from this study as permitted by law. This is necessary to ensure the accuracy of the findings and the safety and welfare of participants. 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 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.

- The sponsor of this study,*[National Institutes of Health]*, and/or its authorized representatives;
- 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); or the IRB that reviewed this research
- 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 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.

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 your 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 medical care or eligibility for future care or membership in KFHP.

Will I receive results from the Fasting Test, 2-hour OGTT Test in this study?
We will provide you with the results of your 2-h OGTT blood test for diabetes or fasting blood test results. We will not provide your research test results to your KP healthcare provider, but the clinical test results will be entered into the electronic medical record for the KP members.

What if I have any questions or problems?
In the 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, 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.

****

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, which includes 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 PARTICIPATE IN THE RESEARCH STUDY AS DESCRIBED IN THIS FORM.

_____ _____

Participant's Signature Date

_____

Participant's Name Printed

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