

KAISER FOUNDATION HOSPITALS
THE PERMANENTE MEDICAL GROUP, INC.
DIVISION OF RESEARCH

ASSENT TO PARTICIPATE IN A RESEARCH STUDY (BIOMEDICAL)

For ages 13-17

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

It's OKAY TO ASK QUESTIONS!

Research is all about asking questions. You might find words in this paper that do not make sense. It's okay for you to ask us to tell you what the words mean. You might also hear this research study called "protocol", "study" or just "research". These words all mean the same thing.

We are asking you to be a part of a research study of young people 9 to 14 years of age. This form will tell you about the study. Please ask us to explain any word or part that you do not understand.

Kaiser Permanente researchers, led by Dr. Erica Gunderson are doing a study to learn about what matters or influences the growth and health of those 9 to 14 years of age, now and during earlier years.

We told your parent(s) about this study, and after we tell you about it, we will ask you if you want to be in this study. It's OK to say "no" if you don't want to be in the study. You will still get medical care without being in this study. You may quit being in this study at any time, and you will still be able to get care here.

What will happen if I agree to take part in this study?

If you say "yes", we will ask you to do a number of things. We want you to come to the clinic for one visit and will also ask you to do some other things away from the clinic visit.

At the clinic, the visit that will take about 2 to 3 hours, the following will happen.

A study staff member will ask you to do the following.



1. Measure your blood pressure and how fast your heart beats (3 times) with a machine, while you are sitting.
2. Measure your height and weight.
3. Do a blood test. A trained lab technician will take blood samples with a needle in the arm. You will give a blood sample and then will be given a sugary drink. Thirty minutes later, you will give another blood sample and then wait another 1.5 hours and give a third sample. While you are waiting, you will be doing other parts of the study.
4. Measure your waist with a measuring tape.
5. Measure fat thickness with a measuring tool that is like a tong, in certain spots including the back of the shoulder, hip, arm and waist. The study staff will grasp or take your skin between her thumb and index finger at back of the shoulder, hip, arm and waist, and measure the thickness. Each measure will be done twice.
6. Measure overall body fat. For the body fat measure, a thin wire will be attached with a small, sticky pad to one hand and one foot to send a very small electrical current through the body. The current cannot be felt.
7. Fill out an on-line food questionnaire about what you ate the day before. It will take about 15 to 20 minutes.
After you leave the study clinic visit, you will be asked to do 2 more food questionnaires on different days.
8. You and your parent will each be asked to fill out 6 questionnaires about your health, how your body is growing and changing, any medicines, and other habits like sleep, exercise and daily activities.

What are the potential harms or risks if I join this study?

It may hurt a little bit when a needle is used to take blood. You may be slightly uncomfortable when the blood pressure cuff tightens around your arm, and when the skin is measured on the different parts of your body. This is not lasting.

You will need to remove some of your clothing for some of the study activities and sometimes this may cause embarrassment. You will be in a private area for these activities and remember that you do not have to answer any questions or do any activities that you do not want to do.

What are the benefits to taking part in the study?

If you are in the study, you probably won't be helped in a direct way. We will give you information about your results of the study activities like height, weight, blood pressure and about your diet. If you are in the study, you will be helping the researchers learn more about what factors affect health that may help others in the future.

What if I have any questions or problems?

You may ask questions any time, now, later and anytime during the study. If you have any questions or problems from taking part in this study, you can always talk to Dr. Gunderson or you can talk to someone on her team at the toll-free number 1-866-279-8624.

Do you have to be in this study?

You don't have to be in this research study if you don't want to. Nobody will be mad at you if you say no. Even if you say yes now and change your mind after you start doing this study, you can stop later if you want.

Be sure to ask Dr. Gunderson to tell you more about anything that you don't understand.

STATEMENT OF ASSENT

_____ has told me what this research study is about. I have read the information in this form. I have thought about being in this research study. I have asked and gotten answers to my questions.

Name of participant (printed):

Name of person conducting assent discussion (printed)

Signature of person conducting assent discussion

Date