Cover Page for Informed Consent Form

Study Official Title: Optimizing a Scalable Intervention to Maximize Guideline-recommended Diabetes Testing After GDM

Study Brief Title: Study to Understand Risk Information to Support and Empower (SUNRISE)

Informed Consent Form approved by IRB on 01/05/2023

SUNRISE Study Consent Form

KAISER FOUNDATION HOSPITALS
THE PERMANENTE MEDICAL GROUP, INC.
(Division of Research)

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE: **S**tudy to **Un**derstand **R**isk **I**nformation to **S**upport and **E**mpower (**SUNRISE**: IRBNet# 1777758)

Please review this information about the study. You will be emailed copies of this information for your records.

If you consent to participate in the study, you will then be directed to Survey 1.

STUDY SUMMARY

Researchers at Kaiser Permanente invite your consent and participation in a voluntary research study. If you choose to participate, you will receive health information about gestational diabetes mellitus (GDM) in addition to your usual medical care. Participants will be randomly assigned (like flipping a coin) to receive different types of this health information. You will be asked to complete 3 surveys about your health, healthcare, and opinions about the health information. Each survey will take about 20 minutes. Participation in the study will last approximately 16 months from the time you join. All study activities can be done online by using your computer, tablet or cellular phone.

The purpose of this study is to learn whether different types of health information impact the number of patients who take advantage of the healthcare services and health care offered by Kaiser Permanente after having gestational diabetes.

Possible benefits of this study include helping to improve how doctors communicate with patients about their health and healthcare. While there are no direct benefits of participating, the risks are minimal. Possible risks include a small chance of loss of privacy and possible discomfort when answering some survey questions. However, you may stop participating in the study at any time. Your health coverage will not be affected.

If you choose not to participate in this study, the Kaiser Permanente researchers may use data from your medical record, without identifiers, in order to know whether the study information

we collect represents the larger group of patients. If you do not submit this consent form and you do not wish for the researchers to use your protected health information (PHI), you may send a letter or email to the study's Project Manager, Andrea Millman, MA, stating that you do not want the Kaiser Permanente researchers to use your data in this study. If we do not hear from you within 10 days of receiving this consent form, we may use your de-identified information to compare study participants with non-participants, even if you do not complete the study.

BEFORE YOU READ THIS CONSENT FORM, YOU SHOULD READ THE KAISER PERMANENTE MEDICAL CARE PROGRAM RESEARCH PARTICIPANTS' BILL OF RIGHTS. Please **click here** to print a copy of the "Research Participants' Bill of Rights" or to save it as a PDF.

Researchers at Kaiser Permanente in Northern California are conducting a 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 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 the study is finished. This process is called "informed consent." This consent form gives information about the research study, which the study staff will discuss with you.

You will also be asked to indicate your approval on 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 study staff to explain any words or information that you do not clearly understand by calling (866) 801-0020.

Who is funding this study?

The research costs of this study are being paid by the study sponsor, the National Institutes of Health (NIH). 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 learn whether different types of health information impact the number of patients who take advantage of the healthcare services and health care offered by Kaiser Permanente after having gestational diabetes.

Why am I being asked to take part in this study?
You were selected because Kaiser Permanente records indicate that you have been diagnosed with gestational diabetes.

How many participants will take part in this study?
We will enroll about 2,000 participants from Kaiser Permanente Northern California.

How long will I be in this study?
Participation will last about 16 months (until 1 year after delivery).

What will happen if I take part in this study?
If you agree to take part in this study and submit this consent form, the following things will happen:

1) Fill out three online surveys
    a. Each survey takes about 20 minutes.
    b. There will be a survey when you enroll in the study, about 2 weeks after delivery, and 12 months after delivery.
    c. Survey questions will ask about your health, healthcare, and opinions about health information.

2) View a unique online health message
    a. You will be randomly assigned (like flipping a coin) to receive a unique health message. Randomization helps ensure that the study groups can be compared to each another.
    b. Viewing the health message takes 10-15 minutes each time.
    c. You will receive the health message about 2 weeks after enrollment and 2 weeks after delivery. You may also receive reminders related to the health message.

To minimize the amount and types of information we ask in the surveys, we will link your responses with information from your electronic health record. The information we collect includes demographics; use of healthcare services (e.g., diabetes screening, lifestyle programs, routine postpartum visits); diagnosis of diseases or conditions; diagnostic, laboratory, and treatment information; use of the kp.org patient portal; your weight and height; and perinatal complications. These data will be used for the duration of this study.

You will have the option to be contacted for follow-up studies. You may still participate in this study, even if you do not wish to be contacted for future studies.

Out of respect we will no longer contact you if you experience a pregnancy loss or infant loss.

Will the information collected be used in future research?
You have the option of providing consent for Kaiser Permanente researchers to use your data from this study for future research activities. The information will be stored indefinitely and

may be used and shared in the future for research. You may still participate in this study even if you do not consent to researchers using your data for future research.

What are my responsibilities while I am in this study?
You will be asked to complete 3 surveys and view a unique health message.

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

- Some of the survey questions may seem very personal. However, the surveys are based on established research instruments that have been used in prior studies. To our knowledge, no studies have found these instruments to be more than minimally upsetting. You have the right to stop participating at any time.
- The health message mentions issues that may be sensitive for some participants. However, the health message is designed to be positive and non-judgmental.

In addition to the risks and discomforts listed here, there may be other risks that are currently not known, or risks that we did not anticipate, associated with being in this study.

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, a limited portion of your information is going outside Kaiser Permanente to collaborating research organizations. 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?
There will be no direct benefit to you from participation in this study. However, it is hoped that the study results will help improve patients' health and healthcare in the future.

What are my choices if I do not want to be in this study?
This research is not designed to diagnose, treat or prevent any disease. You can choose not to participate in the study at any time. Your health coverage will be not affected.
If you choose not to participate in this study, the Kaiser Permanente researchers may use data from your medical record without identifiers in order to know whether the information we get represents the larger group of patients. If you do not submit this consent form and you do not wish for the researchers to use your protected health information (PHI), you may send a letter or email to the study's Project Manager, Andrea Millman, MA, at 2000 Broadway, Oakland, CA, 94612 or Andrea.Millman@kp.org, stating that you do not want the Kaiser Permanente researchers to use your data in this study. If we do not hear from you within 10 days of receiving this consent form, we may use your de-identified information to compare study participants with non-participants, even if you do not complete the 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. 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 Kaiser Foundation Health Plan.

If you decide that you no longer wish to continue in this study, you will be requested to notify the study staff by phone, email, or in writing.

If you leave the research study, information collected while you were in the study will not be removed from our records.

Will there be any costs to me to take part in this study?
You will need access to the internet to view the health message and to complete the surveys. You will be responsible for any costs associated with accessing the internet.

All aspects of your standard medical care will continue to be provided to you according to the terms of your plan benefits, as 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?
You will receive $80 in gift cards to thank you for doing all 3 surveys: $30 for survey 1, $20 for survey 2, and $30 for survey 3.

What will happen if I am injured during the study?
This study only involves collection of information and does not involve any treatment, or the use of any drugs, devices, or procedures. Therefore, we do not expect that you would experience any injury.

Will my information be kept confidential?
Efforts will be made to keep your personal information confidential. However, your personal information may be disclosed if required by law, or otherwise indicated in this consent form.

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 (NIH) 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, such as use of data from your electronic health record as described above, including: demographics; use of healthcare services; diagnostic, laboratory, and treatment information; your weight and height; and perinatal complications.

To the extent permitted by law and by indicating your approval on 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 (the National Institutes of Health) and/or its authorized representatives
- The 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

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 hospital/study site. All coded records will be kept confidential and stored in a secure area.

If you decide to participate in this study, you will also be giving consent for the medical research investigator or his/her assistants to review your medical records as may be necessary for this study.

Research records may be kept as part of your electronic medical record, subject to the privacy

laws that control medical records, but accessible to medical staff as needed.

Your identity will not be revealed in any publication or release of study results.

Will I receive new information about the study while participating?
During the course of the study, you will be informed of any important new findings (either good or bad) such as changes in the risks or benefits resulting from participation in the research, or new alternatives that might change your mind about your continued participation in the study. You may be asked to indicate your approval on a new consent form if additional risks are found.

Where can I get more information?
A description of this study will be available on https://ClinicalTrials.gov/, as required by U.S. law. This website will not include any information that can identify you. At most, the website will include a description of the progress of the study and a summary of the results. You can search this website at any time.

What if I have any questions or problems?

In case of study-related questions, problems, or injuries, you can contact the study staff at (866) 801-0020 or SUNRISE@kp.org; the study Project Manager, Andrea Millman, MA, at Andrea.Millman@kp.org; or the investigator responsible for the study within Kaiser Permanente in Northern California, Assiamira Ferrara, M.D., Ph.D., at Assiamira.Ferrara@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, kpnc.irb@kp.org or 1-866-241-0690.

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PERMISSIONS FOR DATA SHARING

Data Sharing
Please indicate your choice below for whether information collected in this study may be used for future studies, such as studies related to women's and children's health. If used, your data will never contain information that can identify you. You do not have to agree to this data sharing option to participate in this study.

o Yes, my information may be used by Kaiser Permanente and collaborating researchers for future studies related to women's and children's health.
o No, I do not want my data to be used for future research studies.

CONSENT TO BE IN THE STUDY

I have read (or someone has read to me) the above. I am satisfied with my understanding of the study and 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.

BY CLICKING 'YES' BELOW, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH STUDY AS DESCRIBED IN THIS FORM.

o Yes, I would like to participate in this study.

o No, I do not want to participate in this study.

PERMISSIONS FOR FUTURE STUDIES

Contact for Future Studies

Please indicate your choice below for whether we may contact you to participate in future studies. You do not have to agree to this option to participate in this study.

o Yes, Kaiser Permanente researchers from this study may contact me to participate in future studies.

o No, I do not want the researchers from this study to contact me about future studies.

Please click "Next" to read an authorization form and enroll in the study.