INFORMED CONSENT FORM

Official Study Title: Strategies to Improve Postpartum Screening for Dysglycemia in Women with Gestational Diabetes: Electronic Reminders and Alternative Diagnostic Criteria

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Institution: Obstetrics Clinic – Hospital das Clínicas, University of São Paulo Medical School (HC-FMUSP), São Paulo, Brazil

Principal Investigator: Tatiana Assunção Zaccara, MD, PhD

HOSPITAL DAS CLÍNICAS, UNIVERSITY OF SÃO PAULO MEDICAL SCHOOL (HC-FMUSP)

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RESEARCH INFORMATION

Study Title:
Strategies to Improve Postpartum Screening for Dysglycemia in Women with Gestational Diabetes: Electronic Reminders and Alternative Diagnostic Criteria

Principal Investigator:
Dr. Tatiana Assunção Zaccara

Department/Institution:
Obstetrics Clinic, Hospital das Clínicas, University of São Paulo Medical School (HC-FMUSP)

You are invited to voluntarily participate in the research project entitled *"Strategies to Improve Postpartum Screening for Dysglycemia in Women with Gestational Diabetes: Electronic Reminders and Alternative Diagnostic Criteria."*

The purpose of this study is to evaluate the impact of WhatsApp reminder messages on attendance rates for the 75-gram oral glucose tolerance test (OGTT) in the postpartum period, as well as to compare the prevalence of glycemic abnormalities identified using two different diagnostic strategies: the traditional method (fasting and 2-hour glucose levels) and a new approach (fasting and 1-hour glucose levels).

This study is justified by the low rate of attendance for postpartum OGTT and by limitations of the current diagnostic protocol in detecting glycemic abnormalities after delivery. Evidence suggests that reminder systems may increase attendance rates and that the alternative diagnostic strategy may improve early detection of metabolic alterations.

Participants will be randomly assigned to one of two groups and may or may not receive reminder messages for the postpartum OGTT. If you are assigned to the intervention group, you will receive WhatsApp reminders 7 days and 3 days before the scheduled test date. If you do not attend the test, an additional reminder will be sent the following day offering the option to reschedule. If the test is rescheduled at that time, no further reminders will be sent. If rescheduling occurs before the original test date, reminders will still be sent at 7 and 3 days before the new date. All reminders will include a request for confirmation of receipt.

Regardless of group assignment, all participants will undergo a 75-gram OGTT between 6 and 12 weeks postpartum, with blood samples collected at three time points: fasting, 1 hour, and 2 hours after glucose ingestion.

If you are assigned to the intervention group, you may benefit directly from receiving reminder messages. Otherwise, even without reminders, you may benefit indirectly through early detection of prediabetes or diabetes that might not be identified using the current protocol. The study may also contribute to improving future screening strategies and long-term metabolic outcomes.

This research does not involve additional risks or costs. Participants will remain anonymous in all publications and reports. The research team will maintain confidentiality and will use the data solely for academic and scientific purposes. Your personal data will not be disclosed under any circumstances, in accordance with the Brazilian General Data Protection Law (Law No. 13,853/2019).

The only possible discomfort is the collection of one additional blood sample (at 1 hour after glucose ingestion), compared to the standard protocol. However, any potential harm or additional cost will be fully compensated, in accordance with National Health Council Resolution No. 466/2012.

You are free to refuse participation or withdraw your consent at any time, without any penalty or impact on your medical care, and with full assurance of privacy and confidentiality.

If you agree to participate, this informed consent form will be prepared in two identical copies and duly signed and initialed by you and the responsible investigator (or a delegated team member). One copy will be given to you, and the other will be kept by the research team for five years after the end of the study.

If you have any questions or concerns regarding the ethical aspects of this research, you may contact the Research Ethics Committee (CEP) at:
Rua Ovídio Pires de Campos, 225 – 6th floor
Phone: +55 (11) 2661-7585 / 2661-1548
Hours: Monday to Friday, 7:00 AM to 4:00 PM
Email: cappesq.adm@hc.fm.usp.br

I have been adequately informed about the study *"Strategies to Improve Postpartum Screening for Dysglycemia in Women with Gestational Diabetes: Electronic Reminders and Alternative Diagnostic Criteria."*

I have discussed the information above with the Principal Investigator (Dr. Tatiana Assunção Zaccara) or her delegated team members (Bruna Sant' Ana Beage and Beatriz Tauany da Silva). I understand the objectives, procedures, potential risks and discomforts, and the guarantees provided.

I voluntarily agree to participate in this study, sign this informed consent form, and receive a signed copy from the investigator.

Participant / Legal Representative Signature: _____
Date: ____ / ____ / _____

Participant / Legal Representative Name: _____

Investigator Signature: _____
Date: ____ / ____ / _____