COVER LETTER

Official Title: A Telemedicine Prenatal Care Model on Low Risk Pregnants: The m@Mae-e Study.

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FREE AND INFORMED CONSENT FORM FOR CLINICAL RESEARCH
M@MÃ-E RESEARCH PROTOCOL
VERSION 1.0 – FEBRUARY, 23, 2023

Principal Researcher: [redacted]
Contact: [redacted]

INVITATION AND IDENTIFICATION OF THE STUDY

You are being invited to participate voluntarily in the study entitled: **"Prenatal care by telemedicine: adequacy of maternal-fetal care guidelines in the context of the COVID-19 pandemic"**. This document is intended to inform you about the possibilities of risks and benefits of the study and confirm your participation through the free and informed consent form. If you have any questions, please feel free to **contact the professionals involved and clarify your doubts**. The decision to participate in the study is voluntary and you can refuse or withdraw from the study at any time without any consequences for **your treatment, which will be maintained, without any prejudice.**

SITUATION OF THE CURRENT KNOWLEDGE

Due to the COVID-10 pandemic, it has been recommended that pregnant women carefully follow the measures of social distance and prevention of contagion, leaving home to attend prenatal consultations and to carry out exams has become a potentially dangerous task, with a higher risk of contagion by SARS-Cov-2.

On the other hand, maternal-fetal care is essential, studies developed in the United Kingdom have shown that pregnant women who do not attend prenatal services are at greater risk of **maternal death, newborn death and other complications.**

The peripartum period is a time of greatest risk for women regarding feelings of distress, anxiety, stress and depression; this moment of pandemic, particularly stressful, increases the risk that some women will develop new symptoms or experience exacerbation of preexisting symptoms and anxiety disorders.

In Brazil, prenatal care follows recommendations from the Ministry of Health, which **recommends** at least 06 (six) prenatal consultations for low-risk pregnant women **(without previous diseases and with low risk of developing complications)**, to be carried out in the health care unit or home visits. Several studies carried out around the world have shown that the use of teleconsultation and telemedicine is safe for monitoring low-risk pregnancies, reducing stress and increasing satisfaction among patients.

RESEARCH OBJECTIVES

The COVID-19 pandemic brought out the need to modernize the Brazilian prenatal care model. The development of a protocol for hybrid prenatal care, combining reduced in-person consultations and remote monitoring through the use of wearable technologies **(devices with sensors to monitor clinical signs)**, results in lower cost and risk exposure, without reducing the quality of care. The objectives of this research are to compare anxiety in pregnant and puerperal women and cost-utility in a hybrid prenatal care model and in a traditional care model.

PROCEDURES TO BE CARRIED OUT

This study will be carried out with pregnant women attending prenatal care at usual risk, between 2023 and 2025, by comparing the model of exclusively in-person consultations and the hybrid care model (combining in-person consultations, which will be maintained when essential, and consultations by telemedicine, combined with the use of equipment to assess blood pressure and fetal heart rate at home.

Low-risk pregnant women who accept to participate in the study will be randomly selected (also understood as "random" for the hybrid prenatal group (with in-person consultations and distance consultations) or for the in-person prenatal group (with all face-to-face consultations). Patients allocated to hybrid care will accomplish at least

six face-to-face consultations and three online consultations. Patients selected for the traditional model will carry out between 06 and 09 in-person consultations.

If the pregnant woman selected for the hybrid model does not adapt or does not feel comfortable with telemedicine care, she may request for all her consultations to be carried out exclusively in person; your will will be respected, and there will be no harm to your follow-up and treatment.

The research will be carried out at outpatient H of Hospital Santa Clara, at the Hospital Complex of Irmandade Santa Casa de Misericórdia de Porto Alegre, located at street Annes Dias, 295 - Centro Histórico, Porto Alegre - RS, zip code 90020-090 and at the Federal University of Health Sciences of Porto Alegre, located at street Sarmento Leite, 245 - Porto Alegre, Rio Grande do Sul, Brazil - zip code 90050-170.

BENEFITS AND RISKS OF TREATMENT

All pregnant women in the study will receive care from the same team, which will include resident doctors and preceptor doctors. All of the required laboratory and imaging tests will be made at the hospital, in a standardized way, that is, the standard of care will be exactly the same for both groups. Benefits include **access to an app (for cell phones)** to monitor the progress of pregnancy, with **information** about pregnancy, childbirth and the postpartum period and the right to have two postpartum consultations at the Prenatal Outpatient Clinic. .

The possible risks are minimized by the equipment that will be made available for the assessment of blood pressure and fetal heart rate at home. The risk is also minimized by free access to the Obstetric Emergency, 24 hours a day, 7 days a week, for all participants, from both groups.

VOLUNTEERING

Your participation is voluntary and you can withdraw your consent or **discontinue your participation in the study** at any time, if you prefer, without penalty and/or prejudice of any nature, **prenatal care would be maintained normally.** That will be no cost to you from this study, as well as that will not be any kind of remuneration for your participation. If an injury or any harm occurs as a result of your participation in this research, full assistance will be available at no cost to you.

PARTICIPANT'S DUTIES

Just as you have rights, by participating in the research, we would like to reinforce your main obligations: attend all appointments on the scheduled date, follow the study schedule, to accomplish the requested procedures and use medications (if possible) correctly, as directed the team responsible for your care; inform the researcher of any change in health that occurred and the medications used in the period; report any unexpected effects to the researcher as soon as possible and, when appropriate, **take care** of the equipment made available for home use.

PRIVACY AND CONFIDENTIALITY

The doctors and researchers will have access to your data, however, your anonymity is guaranteed and possible scientific publications resulting from this study will not identify you under any circumstances as a participant. The data obtained will be treated under strict confidentiality conditions. The data may also be shared with the following groups/persons associated with this research study or involved in research review: other research team staff, Clinical Research Center, Research Ethics Committee and Legal Department; also with government representatives or federal agencies, when required by law. If new information arises that may be important to your decision to continue the research, you or your legal representative will be informed as soon as the data becomes available.

COSTS

You will not have any additional costs to participate in this study.

ETHICAL ISSUES

This study was approved by the Research Ethics Committee, whose function is to ensure the ethics of studies involving human beings. For any general questions and/or questions related to the participant's rights (right to clear

information, related to costs, medical and hospital follow-up in case of damages resulting from participation in the research, data confidentiality, access to results), contact the Research Ethics Committee of the Irmandade Santa Casa de Misericórdia de Porto Alegre – coordinated by Dr. [redacted], Address: Avenue Independência, 155 - 6th floor - Dom Vicente Scherer Hospital – POA/RS.

CONTACT

For any questions related to the study, please, feel free to contact the doctors responsible for conducting the study or Dr. [redacted] on the phone: [redacted].

I declare that I have been informed of all details related to the study to which I will be submitted.
I will receive a signed and dated copy of this Free and Informed Consent Form.

_____

Full name and Individual Taxpayer Registration of the research participant

_____

Signature of the research participant

_____

Full and legible name of the responsible researcher

_____

Signature of the responsible researcher

By signing below, you confirm that you have read the statements contained in this consent form, that the study procedures were explained, that you had the opportunity to ask questions, that you are satisfied with the explanations provided and that you have voluntarily decided to participate in this study. One copy will be given to you and the other will be filed by the principal investigator.

_____

Signature of the research participant

_____

Place and date