São Paulo State University (UNESP) – "Júlio de Mesquita Filho"

Botucatu Medical School – Department of Pathology

Laboratory of Immunopathology of the Maternal-Fetal Relationship

Research Project

Systematic Screening of Lower Genital Tract Infections in Pregnant Women for Gestational and Neonatal Outcomes: a Randomized Controlled Trial

NCT Number:NCT07592286

March 16th 2026

TCLE — Legal Guardian

Dear legal guardian,

You are being invited to authorize the participation of the person under your responsibility in the research study entitled **"Systematic Screening for Lower Genital Tract Infections in Pregnant Women for Gestational and Neonatal Outcomes: a randomized controlled trial,"** conducted by Rita de Cássia Fossati Silveira Evaldt, researcher at the Federal University of Pampa – UNIPAMPA, Uruguaiana Campus.

The main objective of this study is to evaluate whether systematic screening for asymptomatic genital infections during prenatal care can reduce the occurrence of unfavorable gestational and neonatal outcomes.

The person under your responsibility is being invited to participate because she is a pregnant woman in the first trimester of pregnancy, which are the inclusion criteria established for this study. Participation is voluntary and not mandatory. Both the participant and you, as her legal guardian, have full autonomy to decide whether or not she will participate, and consent may be withdrawn at any time, without any harm to health care.

The pregnant participant's participation will consist of a clinical interview with collection of sociodemographic, obstetric, and clinical information, as well as gynecological examinations similar to those already performed during prenatal care. Vaginal material will be systematically collected at all prenatal appointments, and endocervical material will be collected once in each gestational trimester. Only routine prenatal laboratory tests will be used, including complete blood count; blood typing and Rh factor; indirect Coombs test, when indicated; fasting blood glucose; oral glucose tolerance test, when indicated; serological tests for syphilis, HIV, hepatitis B and C; urinalysis and urine culture; and toxoplasmosis testing, when indicated. After delivery, information about the pregnant woman and the newborn will be collected from hospital medical records.

The interview and clinical procedures will take place during an obstetric appointment, lasting approximately 20 minutes, at the Women's Health referral service or, when necessary, at the participant's Family Health Strategy unit of origin.

Transportation costs to the referral service will be the participant's responsibility. If transportation is not available, the appointment and material collection may be carried out at the participant's primary health care unit of origin.

This research involves minimal risks related to the different stages of data collection, as described below.

During the clinical interview, there may be a risk of emotional discomfort or embarrassment when answering personal questions or questions related to health and pregnancy. To minimize this risk, the interview will be conducted by a trained professional in a private environment, respecting the participant's privacy. The participant will have the right not to answer any question or to interrupt the interview at any time, without any harm to health care.

The collection of vaginal and endocervical material may cause mild physical discomfort, a feeling of pressure, or temporary discomfort during the gynecological examination. These risks will be minimized by having the procedure performed by a qualified obstetric physician, using

appropriate technique, sterile materials, and respecting the principles of comfort and safety for the pregnant woman. If the participant reports pain or discomfort, the procedure will be immediately interrupted, without any harm to prenatal care.

The blood laboratory tests considered in this research correspond exclusively to routine prenatal tests. No additional blood samples will be requested solely for research purposes. Therefore, no additional risks are expected beyond those already inherent to usual prenatal care.

Reviewing maternal and neonatal clinical records does not involve direct contact with participants and does not involve physical risks. There is a minimal risk related to breach of confidentiality of information, which will be mitigated through the use of an anonymized database, restricted access by the research team, and storage of information in a secure environment, in accordance with the Brazilian General Data Protection Law — Law No. 13,709/2018. No social, economic, or legal risks are expected as a result of participation in the study.

Participants may withdraw from the research at any time, without any harm to prenatal follow-up or health care provided by the public health network.

The benefits related to participation include the possibility of early identification and timely treatment of asymptomatic genital infections, as well as contributing to the improvement of prenatal care.

All information collected will be kept confidential and stored in a secure and anonymized database. Only the research team will have access to the information, which will not be used for other purposes.

Considering that this research involves different stages of data collection, I declare that I am aware of and authorize the participation of my dependent in the following activities:

( ) Clinical interview with collection of sociodemographic, obstetric, and clinical information
( ) Collection of vaginal material at all prenatal appointments
( ) Collection of endocervical material once in each gestational trimester
( ) Use of results from routine prenatal laboratory tests
( ) Collection of information about the pregnant woman and the newborn from hospital medical records after delivery

The participant and you, as legal guardian, have the right to receive information about the research at any time and will receive, at the end of the study, a report with the main results.

If any damage occurs as a result of the research, the participant will have the right to compensation in accordance with the Brazilian Civil Code and Resolutions No. 466/2012 and No. 510/2016 of the National Health Council. The data and materials collected will be stored for at least five years and, after this period, will be destroyed. Data collection will take place until July 31, 2028.

This consent form is prepared in two copies, one for the legal guardian and one to be filed by the principal investigator.

In case of questions regarding the ethical conduct of the study, please contact the Research Ethics Committee of UNIPAMPA. The Committee is composed of a group of people whose purpose is to protect the interests, integrity, and dignity of research participants.

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Contact of the principal investigator:
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I declare that I have read and understood the information above and authorize the participation of the person under my responsibility in the research.

Name of the legal guardian: _____
Signature of the legal guardian: _____

Name of the principal investigator: Rita de Cássia Fossati Silveira Evaldt
Signature of the principal investigator: _____

Uruguaiana, ____ day of _____, 2026