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Aurora IRB #: 17-136 Version date: 11-1-2017	Medical Record # _____

The efficacy of probiotics to reduce antepartum group B streptococcus colonization

NCT03696953

Informed Consent Document
June 12, 2019

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EDITED 6/12/19

Subject name: _____ Subject date of birth: _____

Aurora Health Care, Inc.
Consent to Participate in a Research Study

Study Title	***The efficacy of probiotics to reduce antepartum group B streptococcus colonization***
Study Investigator	Marie Forgie DO 414-219-5800 (daytime) 414-219-5800 (24-hour contact number)
Sponsor	National Institute of Health (NIH). National Institute of Child Health and Human Development (NICHD)

Why am I being asked to participate?

You are being asked whether you would like to voluntarily participate in a research study about probiotics to prevent prenatal Group B Streptococcus colonization because you are healthy and pregnant.

This form describes the study and what you would need to do. We will answer any questions you may have so that you can make an informed decision.

What is a research study?

A research study is an experiment, survey, or information collection whose purpose is to answer a specific question, such as:

- Does this work?
- Is it safe?
- What kind of treatment is better?
- How do people think or feel about this?

To answer these questions, doctors and scientists need volunteers to participate in research studies. These volunteers are called "subjects." The doctors and scientists who run the research study are called "investigators." Other people who help them run the study are called the "research team."

Sometimes a supplement being tested makes research subjects better, and sometimes it doesn't. When you are a subject, the main purpose is to see if the study probiotic supplement works. There may be side effects or risks to you, including some we don't know about right now.

A research study has specific rules the investigator must follow. The study rules may say that subjects can't receive certain medications or treatments while they are in the study. We will explain the rules you will have to follow. If you can't or don't want to follow these rules, then you should not participate.

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What is the purpose of this study?
In this study, we want to find out if oral probiotics taken daily during pregnancy can reduce Group B Streptococcus colonization.

Who is sponsoring this study?
The sponsor for this study is the National Institute of Health (NIH). National Institute of Child Health and Human Development (NICHD). The sponsor pays for Drs. Forgie and Hanson and Aurora Health Care to run the study.

Where will this study take place?
This study will take place at Aurora Sinai prenatal clinics and hospital and expects to enroll about 80 subjects.

What is involved?
As a subject, you will be responsible for:
- attending all study visits
- telling the investigator if you are feeling bad
- telling the investigator if you have any changes in medications during the study
- following the directions of the investigator and research team
- taking the study capsule daily
- not taking any other probiotic product during the study

If you agree to take part in this study, you will sign this consent form before any study-related procedures are performed. The investigator and research team will ask you questions and review your medical record to see if you qualify to be in the study.

If you meet all criteria to be in this study, you will be randomized to one of two groups. Randomized means being assigned to a group by chance, like flipping a coin or drawing names out of a hat. You have a 50% chance of being assigned to each group. Group 1 will take a probiotic capsule daily, Group 2 will take a placebo capsule daily. You cannot choose which group you will be in. We will not be able to tell you which group you are in. The investigator and research team will not know your group, either. However, we can quickly find out which group you are in if we ever need to know for your safety.

You may receive a placebo instead of the study probiotic. A placebo looks like the study drug, but does not have active ingredients. Comparing a study probiotic to a placebo helps investigators tell how well the probiotic works.

The following tests are part of regular medical care. This means you will have these whether you choose to be in this study or not.
- One month before your due date (35-37 weeks) you will be tested for Group B Streptococcus (GBS). That test is done by swabbing the vagina and rectum with a cotton swab to determine if you will need to be given antibiotics during labor to prevent your baby from getting GBS. GBS

may cause serious problems for some new born babies. This testing and antibiotic treatment (if GBS positive) is done to prevent newborn problems from GBS.

The following tests are for research purposes only. This means you will only have these if you agree to be in the study:

- **Screening/Randomization: At about 28 weeks pregnant you will** be randomized to study probiotic or placebo
- **Questionnaires:** If you agree to participate in this study-when you are about 28 weeks pregnant, you will receive some questionnaires that will ask you about your diet, your digestion, your personal cleansing practices and about your sex life in the past week. These things will help us understand more about GBS. You may skip any question that makes you uncomfortable.
- **Swabs:** At the same visit you will also have a study GBS culture done by swabbing both the vagina and rectum with a cotton swab. You may perform this test yourself or ask your midwife or doctor to do the swabs for you.
- These questionnaires and tests will be repeated at 35-37 weeks of pregnancy.
- After the birth of your baby we will ask you the same questions but will not perform any swabs.

What will happen at each study visit?

Visit	During this visit, you will	How long is this visit?	Reminders
Visit 1 About 28 weeks pregnant (Screening/Randomization)	• Review and sign this consent form first • Complete questionnaires • Vaginal and rectal swabs • Be randomized to study probiotic or placebo • Receive study bottle to take home	1 1/2 hours	
Visit 2 (Randomization) About 36 weeks pregnant	• Complete questionnaires • Vaginal and rectal GBS swab routine for prenatal care • Vaginal and rectal GBS swabs for study	1 hour	
Visit 3 1-2 days after birth	• Complete questionnaires	30 minutes	Bring your study bottle
2-4 weeks after birth	• Phone call from study coordinator to see how you and the baby are doing	10 min	
2 months to 10 weeks after birth	• Phone call from study coordinator to see how you and the baby are doing	10 min	

Are there any risks to me?

There may be risks, side effects and discomforts if you choose to participate in this study. These can be physical, emotional, financial or social. The ones we know about are listed below.

This study is blinded, meaning that your prenatal provider, the researchers and you will not know if you are taking the probiotic capsules or the placebo capsules (no active ingredients). There may be side effects from the study probiotic capsules such as bloating for a few days. Although side effects from probiotic capsules are very rare, as a part of monitoring your safety, your prenatal provider will regularly ask if you have experienced any side effects including fever (temperature greater than 101.0) while in this study. There may be other side effects that we don't know about yet, so be sure to tell the investigator about any unusual symptoms.

Risks of Florajen3 (Probiotic)
The human body contains many probiotic bacteria. These probiotic bacteria help us stay healthy and can prevent some infections. Florajen3 is a probiotic supplement that contains three different probiotic bacteria that are generally regarded as safe by the United States Food and Drug Administration (FDA). Probiotic bacteria are considered food because they are common in things like yogurt and they remain in your digestive tract. In healthy people probiotics do not enter the blood stream. The Florajen3 probiotic combination (sold in the USA) has been given to humans for many years and has been studied by researchers including those involved in this study. The FDA approved the study of this probiotics in pregnant women and required that the probiotic capsules used in this study will undergo a number of additional tests to assure their safety for you and your baby. Still some people who start a probiotic like Florajen3 may experience a side-effect such as bloating. This is usually temporary and improves after a few days.

Commented [A1]: Are you referring to the pilot study? This is unclear to me.

Risks of Placebo
The placebo capsules contain Microcrystalline Cellulose, a common substance in vitamins. There are no known risks of the placebo capsules.

- **Questionnaire risks:** You will complete questionnaires in this study. Sometimes the questions can make people uncomfortable or bring back bad memories. You may skip any question that makes you uncomfortable.

Are there any benefits to me?
You may or may not benefit from being in this study. Your pregnancy could possibly improve in the following ways: you may have less problems with constipation (bowel movements that are hard and/or hard to pass), you may have a lower risk of having GBS at the end of your pregnancy if you are in the probiotic group. We hope the information learned will help other pregnant patients in the future.

How much will it cost to participate?
In this study, the sponsor will pay for every part of the study.
You or your insurance will have to pay for: Prenatal care, labor and birth care, post birth care as usual.

Will I be paid to participate?
You will receive a $25 dollar gift card at the second study visit and a $75 dollar gift card at the third study visit when you return your study bottle after the birth of the baby, for a total of $100 dollars if

you complete all visits. If you do not complete the study, you will not be paid for the study visits that you missed. We may have to report this payment to the IRS.

How long will I be in the study?

You will be in the study for 5 ½ months but will only take the study capsules for about 12 weeks.

Deleted:

The study may be stopped early by the sponsor, the FDA or the investigator. You could be asked to stop being in the study for any of the following reasons:

- for your safety
- if you do not follow our directions for this study

Do I have to be in this study?

You do not have to be in this study. If you start the study, you may stop at any time. There is no penalty or loss of benefits if you don't want to participate, and your decision won't affect your regular medical care.

You may decide to participate now, but change your mind and withdraw from the study anytime without penalty or loss of benefits. If you decide to withdraw before the last study visit, let the investigator know.

Your only choices are to participate, or not to participate. It is up to you whether you want to be in this study.

What if I am harmed from being in the study?

If you get hurt or sick from being in this study, you should seek medical treatment as needed. Be sure to tell the investigator as soon as possible. We will bill your insurance, if you have any, and you will have to pay your usual copays or deductibles. If you have Medicare, we may send information that identifies you to Medicare. If you do not have insurance or if your insurance does not cover your treatment, we will bill you for the costs of the treatment.

Will my records be kept confidential?

Your study records will be kept as confidential as possible. You can find out more in the section "Information about Confidentiality and HIPAA Authorization."

What if there is new information about this study?

If we learn any new information about this study that might make you change your mind about participating, we will tell you.

If you want to know the results of the study once it is over, you can ask the investigator.

Who oversees this study?

The Aurora Institutional Review Board (IRB) has approved this study. The IRB is a group of people who review all research studies at Aurora to check that they meet federal laws and ethical standards.

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IRB approval only means it is ok for the study to begin. *Only you* can decide if being in this study is the right decision. Feel free to talk about this study with your family, friends and personal doctor before you decide.

Who do I contact?

If …	You should contact	Contact information
You are harmed by the research	Marie Forgie or Aurora Patient-Centered Research	414-219-5800 or 414-385-1873
You have questions about your rights as a research subject	Aurora IRB office	414-219-7744 (outside Milwaukee: 877-219-7744)
You have questions, problems, concerns, information, input or complaints about this research study	Marie Forgie or Aurora IRB office	414-219-5800 or 414-219-7744 (outside Milwaukee: 877-219-7744)

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Information about Confidentiality and HIPAA Authorization

The Privacy Rule of the federal Health Insurance Portability & Accountability Act (HIPAA) is a law that protects the confidentiality of your personal health information. This Authorization describes your rights and explains how your health information will be used and disclosed.

Why is access to my health information being requested?

To help answer the research questions, the investigator and research team will use and store personal health information about you. We are asking your permission to use and share it with others, as explained below. If you don't give this permission, you won't be able to take part in the research study.

What information will be collected and used?

When you are a subject, we will collect health information about you that also includes your name, address, telephone number, or other data that could identify the health information as yours. Under HIPAA, this health information is protected and can't be used without your permission, unless otherwise permitted by law. If you sign this authorization, you are giving permission for Aurora Health Care to use and disclose your personal health information as described below.

The following are examples of personal health information that may be collected for this study:

- results of tests and procedures
- information about your medical conditions and history

The collected information may contain your name, address, telephone number, health plan number, date of birth, medical record numbers, dates relating to various medical procedures, and/or other identifying information.

Who will see my protected health information?

By signing this Authorization, you allow Aurora, Aurora's service providers and the research team to use your personal health information to carry out and evaluate this study. You also allow access to your personal health information (including direct access to your medical records at Aurora) to the following:

Who may have access:	**Purpose:**
The sponsor of the study and anyone working on its behalf	To oversee the study and make sure the information is correct
Aurora consultants and employees, including IRB members	To protect the rights and safety of subjects and make sure the study information is correct
Organizations that regulate research (such as the FDA, Office for Human Research Protections (OHRP), or similar government agencies in the US and other countries)	To make sure applicable laws are being followed
Organizations that grant accreditation to hospitals and research programs	For Aurora to remain accredited

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Will you keep my health information confidential?

We will keep your personal health information as confidential as possible. We will only share it as described above or if required or permitted by law. It is not likely your information will be given to others without your permission. However, once your information leaves Aurora, we can't control how it is used, and it will no longer be covered by the HIPAA Privacy Rule.

Will other people know that I was in this study?

If the results of this study are published, your name or other personal information will not be included.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

How long will my personal health information be used?

Access to your personal health information begins as soon as you sign this form. This authorization expires when the study is finished, data analysis is complete, and the study records have been destroyed

What if I change my mind?

If you don't want us to use and disclose your personal health information anymore, you must let the investigator know in writing. If you need help with this, you can ask the research team or call the Aurora IRB office at 414-219-7744 (outside Milwaukee: 877-219-7744).

If you withdraw permission for us to use your personal health information:

- you can't continue in the research study
- we will stop collecting health information from you
- we will still use and disclose any information that we gathered while you were a subject
- there will not be any penalty or loss of benefits to which you are otherwise entitled

Can I see my study records?

You have the right to see and get a copy of your study records. However, by signing this Authorization, you agree that you will not be able to see your study records during the research study. You can only see them once the whole study is complete. The whole study is expected to last until April 30, 2020

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Subject name: _____

- I have read this form and the research study has been explained to me.
- I have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I agree to be in the research study described above.
- I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record.
- I am not giving up any of my legal rights by signing this form.
-

_____

Subject signature Date Time

_____

Witness signature (if applicable*) Date Time

**Use when the subject cannot read the consent (for example, subject is blind, illiterate, or does not speak English). The witness must be present for the entire consent discussion. The witness signature means that the information in this document was presented to the subject, and the subject appeared to understand it.*

For Site Use only:

- I have carefully explained to the subject the nature and purpose of this study.
- The subject has been given enough time and an adequate place to read and review this form.
- The subject has had a chance to ask questions and receive answers about this study.

_____

Name of person obtaining informed consent (print) Title Phone number

_____

Signature of person obtaining informed consent Date Time

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Risk/Benefit/Alternatives Discussion

I have explained and discussed with the subject or his/her legally authorized representative

- The nature of the research
- Potential risks and benefits
- The alternate treatments available to the subject and the benefits and risks of each

Name of person providing this information (print) Title

Signature of person providing this information Date

DOCUMENTATION OF INFORMED CONSENT:

- ☐ All elements of the study contained in this document were discussed with the subject.
- ☐ The subject had the opportunity to ask questions, all questions were answered, and the subject expressed understanding.
- ☐ The subject gave written informed consent before any research-related procedures began.
- ☐ The subject received a copy of the signed and dated consent form.

Signature of person obtaining informed consent Date

FILE A SIGNED COPY OF THIS FORM IN THE PATIENT'S MEDICAL RECORD (if applicable).
Keep the original in the investigator's research records.
Form IC 701A v. 9-28-17

THIS PAGE IS FOR DOCUMENTATION ONLY. IF GIVEN TO SUBJECTS, IT MAY BE BLANK.