APPROVAL
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UIC UNIVERSITY OF ILLINOIS AT CHICAGO
INSTITUTIONAL REVIEW BOARD

University of Illinois at Chicago
Research Information and Consent for Participation in Biomedical Research
"Pro-Moms" - Mitigating the effects of structural violence on maternal iron status: a randomized controlled pilot study of probiotic supplementation in at-risk pregnant women

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Sponsor: National Institutes of Health, National Institute on Minority Health and Health Disparities

About this research study
You are being asked to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future. You are being asked to be a subject in a research study investigating how taking a probiotic, a type of supplement containing bacteria like what you find in foods like yogurt, can impact a woman's iron status, stress, and mood during pregnancy. You have been asked to participate because you are a woman 18 - 45 years old and you are currently pregnant. We also found that when your iron status was checked after your first prenatal appointment, you had a hemoglobin between 10.0 – 11.9 g/dl which puts you at greater risk for iron deficiency during your pregnancy.

Taking part in this study is voluntary
Your participation in this research study is voluntary. You may choose to not take part in this study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with the University of Illinois Hospital and Health Sciences System (UI Health) and/or University of Illinois at Chicago (UIC).

This consent form will give you information about the research study to help you decide whether you want to participate. Please read this form and ask any questions you have before agreeing to be in the study.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

WHY IS THIS STUDY BEING DONE?	Recent studies have shown that taking a probiotic supplement, a supplement containing bacteria similar to what you find in yogurt, can improve iron absorption from food and supplements containing iron. Recent studies have also shown that probiotics can reduce stress and improve mood. This research is being done to better understand how consuming a probiotic daily with a prenatal vitamin influences maternal iron status, stress and mood during pregnancy and infant's iron status (from cord blood) at delivery. Probiotic supplements are safe to use in pregnancy and the probiotic that we are using in this study is considered safe by the Food and Drug Administration (FDA). The probiotic is not approved, but generally considered as safe by the FDA.
WHAT WILL HAPPEN TO ME DURING THE STUDY?	This study has three study visits at < 20 weeks, 24-28 weeks, and 34-36 weeks of pregnancy. At these visits you will: • Have your weight and height measured • Have your blood drawn • Collect two rectal swabs (optional) • Complete surveys • Collect hair samples (optional) The first day of your 15th-20th week of pregnancy you will begin to take a daily prenatal vitamin and probiotic/or placebo pill. We will ask you about your health by text message weekly for two weeks and then bi-weekly until your first pill check and adherence visit. There are four pill check and adherence visits at approximately 18-19 weeks, 22-23 weeks, 30-31 weeks, and 38-39 weeks of pregnancy. At these visits we will ask you about your health. We will attempt to coordinate all study visits with your prenatal visits. We will meet you at Labor and Delivery to collect cord blood and placenta tissue after your delivery.
HOW MUCH TIME WILL I SPEND ON THE STUDY?	All research visits will take place at the UIC Clinical Research Center space located at 914 S. Wood Street. 2nd floor. We will meet with you on 8 occasions over the next 7 months. The visits will be 30 minutes to 3 hours in length. The first study visit (< 20 weeks of pregnancy) will take approximately 3 hours.

	The follow-up visits (24-28 and 34-36 weeks of pregnancy) will take approximately 2 hours. The pill pick-up and adherence monitoring visit (approximately @ 18-19 weeks, 22-23 weeks, 30-31 weeks, and 38-39 weeks of pregnancy) will take about 30 minutes.
ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?	We cannot promise any benefits to you or others from your taking part in this research. If you are in the group that gets the probiotic, this may work better than the standard treatment for low iron levels. If you are in the group that gets placebo treatment, we do not expect you to get any health benefits from being in this study. It is hoped that the knowledge gained from this research may benefit other pregnant women as well as the fields of nutrition, obstetrics and gynecology, and microbiology. Knowledge gained from this study may advance current research examining how consuming a probiotic supplement during pregnancy can affect maternal iron status during pregnancy and maternal and possibly infant health.
WHAT ARE THE MAIN RISKS OF THE STUDY?	For this study, the main risks to know about are: • Discomfort during blood draws • Discomfort during rectal swab collection • Discomfort during hair sample collection • Uncomfortable feeling during survey completion • Loss of confidentiality For details and a list of risks you should know about, please see the "What Are the Potential Risks and Discomforts of the Study" section below.
DO I HAVE OTHER OPTIONS BESIDES TAKING PART IN THE STUDY?	You have the option to not participate in this study.
QUESTIONS ABOUT THE STUDY?	For questions, concerns, or complaints about the study, please contact Mary Dawn Koenig, PhD, RN, CNM at (312) 996-7942 or email at marydh@uic.edu. If you have a research related injury, you should immediately contact Mary Dawn Koenig, PhD, RN, CNM at (312) 996-7942. If you have questions about your rights as a study subject; including questions, concerns, complaints, or if you feel you have not been treated according to the description in this form; or to offer input you may call the UIC Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

	If you have questions or concerns regarding your privacy rights under HIPAA, you should contact the University of Illinois HIPAA Privacy Office at (844) 341-2201 or hipaa@uillinois.edu.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research. Please also feel free to ask the study team questions at any time.

Each study visit and the intervention is described below:

1. **First Study Visit (< 20 weeks of pregnancy)**

You will be called 2-3 days before the first study visit. You will be asked to not eat for at least 2 hours before the appointment.

After you sign the informed consent form, you will be weighed, your height will be measured, and you will be asked to provide a blood sample (from a vein in your arm). The research staff will take about 6 teaspoons of your blood. We will use the blood to measure your iron status and other markers related to how your body handles iron as well as markers of stress. If you agree, we will also take a small sample of hair (70-100 strands) from the top of your head to measure a marker of stress called cortisol. Next you will complete a series of questionnaires. The questionnaires will be about you and your health history, including previous pregnancies, menstruation, medications, and alcohol and tobacco use, your mood, early childhood experiences, stress, experiences of discrimination, spirituality, social support, and experiences of violence, neighborhood factors, residential history, and your diet. The diet surveys will ask you about the foods you ate most often during the past 3 months and about the food and drinks you had the previous day. If you agree, using the provided kit, you will collect two rectal swabs. We will measure the bacteria present and will look specifically for the probiotic bacteria that we are testing.

☐ I agree to allow the researcher to take a hair sample and complete a hair care survey.
Initials _____

☐ I DECLINE to allow the researcher to take a hair sample and complete a hair care survey.
Initials _____

☐ I agree to allow the researcher to use rectal swabs to measure the bacteria present.
Initials _____

☐ I DECLINE to allow the researcher to use rectal swabs to measure the bacteria present.
Initials _____

2. **Probiotic supplement intervention groups (15-20 weeks of pregnancy – labor and delivery).**

Following the first study visit, you will be placed in one of two groups at random, similar to flipping a coin. You will not know what group you are assigned to, but a member of the study team will know your group assignment. You will be assigned to one of the following groups: ***Prenatal vitamin + probiotic/or placebo capsule***. Starting in your 15th-20th week of pregnancy, we will ask you to take a prenatal vitamin and a probiotic capsule or prenatal vitamin and placebo

capsule once daily through your labor and delivery. You will be asked to take both pills in the evening, with dinner and a room temperature or cold beverage. The probiotic is from NatureMade (Pharmavite) and contains the probiotic Lp299v. The prenatal vitamin provided will be from NatureMade (Pharmavite). The prenatal vitamin is similar to a standard prenatal plus vitamin prescribed by clinicians at UIC. The placebo will taste and look the same as the probiotic but will not contain the probiotic. The probiotic is a freeze-dried formulation in a capsule. The pills will be provided in separate containers and labeled as "Vitamin" and just generically as "Probiotic"; both containers will have a cap that tracks your use of the vitamin and probiotic supplements. You will receive 30-40 pills at a time. You will be asked to start taking the pills the first day of your 15th-20th week of pregnancy. We will give you more pills during the follow-up research visits and at 4 additional pill pick up visits as described below. Whenever possible we will schedule a pill pick up during a scheduled standard care prenatal visit. While you are in the study, we will also ask you about any changes to your health, your bowel habits, and if any stomach problems have occurred. While you are in the study, we will ask you to refrain from Activia yogurt, Kefir, fiber supplements, other probiotic supplements (i.e., Tropicana Probiotics and Good Belly products), and all other vitamin and mineral supplements, including omega-3 supplements. Supplements prescribed by your doctor, like folate, are allowable. If at any time in your pregnancy your practitioner prescribes you an additional iron supplement, you are no longer eligible to participate in the study.

3. Follow-up visits (24-28 and 34-36 weeks of pregnancy)

You will be called 2-3 days before the follow-up research visit. You will be asked to not eat for at least 2 hours before the appointment and to bring your pill bottles with you.

During these visits, you will be weighed, and you will be asked to provide a blood sample (from a vein in your arm). The research staff will take about 6 teaspoons of your blood. We will use the blood to measure your iron status and other markers related to how your body handles iron as well as markers of stress. If you agree, we will also take a small sample of hair from the top of your head (70-100 strands) at the 34-36 weeks visit only. Next you will complete a series of questionnaires. The questionnaires will be about your diet, mood, stress, and experiences of discrimination, social support, and experiences of violence. The diet survey will ask you about the foods you had the previous day. If you agree, using the provided kit, you will collect two rectal swabs. We will measure the bacteria present and will look specifically for the probiotic bacteria that we are testing. We will also review your UIC health record to be sure there have been no changes in your health, medication use, or pregnancy.

During these visits, we will also monitor your adherence to the vitamin and probiotic supplements by downloading information from your bottle caps and counting the number of pills you have remaining. You will get a new 30-40-day allotment of pills. If we find that you are not compliant with the pills (you are taking consuming fewer than 75% of pills), we will ask your permission to send you daily text message reminders around dinner time to help increase compliance with the vitamin and probiotic supplement intervention.

☐ I agree to allow the researcher to take a hair sample and complete a hair care survey.
Initials _____

☐ I DECLINE to allow the researcher to take a hair sample and complete a hair care survey.

Initials _____

☐ I agree to allow the researcher to use rectal swabs to measure the bacteria present.

Initials _____

☐ I DECLINE to allow the researcher to use rectal swabs to measure the bacteria present.

Initials _____

4. **Tolerability of vitamin and probiotic supplements (weekly 16-19 weeks, biweekly through delivery)**

It's unlikely that you will experience adverse symptoms from taking a probiotic during pregnancy. However, we will call, text, or email you to find out how you are tolerating the vitamin and probiotic supplements. We will ask you questions about any changes in your health status and if you're having any digestive issues.

5. **Pill pick up and adherence monitoring visits (approximately @ 18-19 weeks, 22-23 weeks, 30-31 weeks, and 38-39 weeks of pregnancy).**

We only give you 30-40 days of pills at a time and we want to monitor your use of the pills throughout the study. We will ask you to come in around 18/19, 22/23, 20/31 and 38/39 weeks of your pregnancy to monitor your pill use and to give you more pills. Whenever possible, we will schedule these visits around prenatal care appointments. If not, separate pill pick up visits will be coordinated or a member of our research team will deliver them to you. All pill pick up visits will occur at the Clinical Research Center space. During these visits, we will also monitor your adherence to the pills by downloading information from your bottle caps and counting the number of pills you have remaining. You will get a new 30-40-day supply of pills. If we find that you are not compliant with the pills (you are taking consuming fewer than 75% of pills), we will ask your permission to send you daily text message reminders around dinner time to help increase compliance with the vitamin and probiotic supplement intervention. We will also ask about your health including nausea, vomiting, and diarrhea.

6. **Labor and delivery**

We ask that you call research staff once you arrive at the UIC Labor and Delivery unit. Once you are admitted to the Labor and Delivery unit, hospital staff will do a blood draw from your arm and two extra tubes of blood will be collected for the study (6 teaspoons). We will use this blood to measure your iron status and other markers related to how your body handles iron. Immediately following your delivery, a member of the research team will collect umbilical cord blood (6 teaspoons) and the placenta. If you choose to bank your umbilical cord blood for future use, we will draw blood from the placenta instead (6 teaspoons). The umbilical cord blood or placental blood will be used as a surrogate for measuring your baby's iron status and markers related to how your baby's body handles iron, and the baby's production of new red blood cells. From your placenta, we will examine markers of how iron is transferred across the placenta to your baby. We will also review your medical record and get information about your labor and delivery including information about your iron status, the length of your delivery, any delivery complications, your baby's gender, your baby's weight, your baby's length, and health.

7. **Final pill bottle drop off at the 6-week postpartum visit**

We will meet you at your 6-week postpartum visit to pick up the pill bottle from you. You will be called and/or texted 2-3 days before your appointment to remind you to bring your pill bottle with you.

Blood, placenta, and rectal swabs banking

As newer laboratory technology emerges, researchers might want to perform additional tests on the blood and rectal swab samples (optional) you provided for this study, which will be stored long term if you agree. This could help us learn more about woman's health during pregnancy. If you agree, the samples provided as part of this study (your blood and rectal swabs) will be stored with linked codes in a secure password-protected database owned by the Principal Investigators and the research staff. Any future use of the samples would be reviewed and approved by an Institutional Review Board.

There is a chance that the samples that you are donating under this study may be used in other research studies, including genetic analyses and may have some commercial value. Should your donated sample(s) lead to the development of a commercial product, UIC will own it and may take action to patent and license the product. UIC does not intend to provide you with any compensation for your participation in this future study nor for any future value that the samples you have given may be found to have. You will not receive any notice of future uses of your sample(s).

☐ I agree to allow my EXTRA BLOOD to be kept by Dr. Mary Dawn Koenig in the College of Medicine Research Building at the University of Illinois at Chicago for use by other researchers for future research to learn more about how to prevent, detect, or treat other health problems in pregnancy.
Initials _____

☐ I DECLINE to allow my EXTRA BLOOD to be kept by Dr. Mary Dawn Koenig in the College of Medicine Research Building at the University of Illinois at Chicago for use by other researchers for future research to learn more about how to prevent, detect, or treat other health problems in pregnancy.
Initials _____

☐ I agree to allow my RECTAL SWABS to be kept by Dr. Mary Dawn Koenig in the College of Medicine Research Building at the University of Illinois at Chicago for use by other researchers for future research to learn more about how to prevent, detect, or treat other health problems in pregnancy.
Initials _____

☐ I DECLINE to allow my RECTAL SWABS to be kept by Dr. Mary Dawn Koenig in the College of Medicine Research Building at the University of Illinois at Chicago for use by other researchers for future research to learn more about how to prevent, detect, or treat other health problems in pregnancy.
Initials_____

☐ I agree to allow my CORD OR PLACENTA BLOOD to be kept by Dr. Mary Dawn Koenig in the College of Medicine Research Building at the University of Illinois at Chicago for use by other researchers for future research to learn more about how to prevent, detect, or treat other health problems in pregnancy.
Initials _____

☐ I DECLINE to allow my CORD OR PLACENTA BLOOD to be kept by Dr. Mary Dawn Koenig in the College of Medicine Research Building at the University of Illinois at Chicago for use by other researchers for future research to learn more about how to prevent, detect, or treat other health problems in pregnancy.
Initials_____

☐ I agree to allow my PLACENTA TISSUE to be kept by Dr. Mary Dawn Koenig in the College of Medicine Research Building at the University of Illinois at Chicago for use by other researchers for future research to learn more about how to prevent, detect, or treat other health problems in pregnancy.
Initials _____

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Initials _____

☐ I agree to allow the researchers to contact me about future research.
Initials _____

☐ I DECLINE to allow the researchers to contact me about future research.
Initials _____

What are the potential risks and discomforts?
The potential risks and discomforts expected in this study for you include the following:

Your risks
1) Blood draws. Some people may be uncomfortable with having their blood drawn and may feel lightheaded, dizzy or even faint. Other risks and discomforts associated with drawing blood from a vein include pain or bruising at the site of the blood draw and rarely, infection at this site. Care will be taken to reduce these risks by having a research team member or team nurse trained in phlebotomy conduct the blood draw.

2) Body measurements (weight). You may feel embarrassed or uncomfortable having your weight measured. To make you feel more comfortable it will be done in a private area and by a trained and experienced researcher.

3) Loss of confidentiality. Because you are sharing personal information, there is always the possibility that confidentiality will be violated. However, every precaution will be taken to keep your information safe. You will be given a unique study ID number to protect your identity. All paper-based data (e.g., consent form) will be stored in locked filing cabinets and any electronic data will be stored in a password protected, restricted access electronic database. The blood and rectal swabs will be stored in a locked laboratory at UIC in a locked freezer. The survey data will be directly entered into a password protected research database. Only authorized research personnel will have access to this data.

4) Questionnaires. Responding to study questionnaires is not expected to but may provoke uncomfortable feelings or cause mild distress. If you experience any of these symptoms you may choose not to answer any question that causes discomfort, or may choose to withdraw from the study altogether. If your responses to the questionnaires indicate you may have depression or anxiety, it is our standard practice to refer you back to your clinical caregiver for further screening and evaluation.

5) Stomach and gastrointestinal (GI) problems from prenatal vitamins containing iron. Some women may experience constipation, nausea, dark or green stools, and even vomiting when consuming prenatal supplements that contain iron. We will closely track any changes in your GI symptoms at the 24-28 and 34-36-week research appointments and pill pick up visits. If you experience nausea, we may suggest that the prenatal vitamin be broken in half and a dose taken in the morning and evening with food and cold or room temperature water. You will take the prenatal vitamin with food so it should help to minimize these symptoms.

6) Taking a probiotic supplement in pregnancy. Although it is marketed as a GI health supplement for pregnancy, the probiotic we are testing is a live bacterial species that is not evaluated or regulated by the FDA. No known side-effects have been reported, there is little research data pertaining to this product in pregnant populations. We will closely track any changes in your GI symptoms at the 24-28 and 34-36-week research appointments and pill pick up visits.

7) Donating rectal swabs. If you agree, we will take two rectal swabs at each study visit (i.e. baseline, 24-28 weeks and 34-36 weeks).You may be uncomfortable or embarrassed about collecting rectal swabs for the study and/or having them stored for potential future research. You may also feel a little discomfort when collecting your rectal swabs. In some cases, a small amount of bleeding may occur if you stick the swab in too far or use too much pressure. There are no known health risks for you or your baby when collecting rectal swabs.

8) Hair sample. If you agree, we will take 70-100 strands of your hair. The sample will be cut close to your scalp using sterilized scissors from the back of your head from several locations midway between the crown and nape of your neck. You may feel some discomfort or light pulling as hair is sectioned off for cutting. A trained staff member will conduct the hair strand sampling.

9) Genetic testing of banked samples. If you agreed to allow us to bank your blood, cord blood, rectal swabs, and/or placenta there is a possibility that we may conduct genetic testing in the future on these samples. There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination if you have already been diagnosed with the genetic disease being tested.

There is a risk that someone could get access to the genetic information we have stored about you. Genetic testing can create information about a subjects' and their families' personal health risks and can cause or increase anxiety, and/or interfere with your ability to get insurance or a job and can even lead to discrimination. Patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/her blood relatives. There are laws against this kind of misuse, but they may not give full protection. There may be other unforeseen privacy risks. We believe the chance these things will happen is very small, but we cannot make guarantees. Your privacy and the confidentiality of your data are very important to us and we will make every effort to protect them.

Will I be told about new information that may affect my decision to participate?
During the course of the study, you will be informed of any significant new research findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

What about privacy and confidentiality?
The people who will know that you are a research subject are members of the research team, and if appropriate, your physicians and nurses. No information about you, or provided by you, during the research, will be disclosed to others without your written permission, except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care or when the UIC Office for the Protection of Research Subjects monitors the research or consent process) or if required by law.

Study information which identifies you and the consent form signed by you will be looked at and/or copied for examining the research by:

- UIC Office for the Protection of Research Subjects, State of Illinois Auditors

A possible risk of the research is that your participation in the research or information about you and your health might become known to individuals outside the research. Any record of your participation in this study will be maintained and kept confidential to the extent permitted by law. The samples, questionnaires and information collected will have only your unique identification number without any name or identifying information. Only the principal investigator, Mary Dawn Koenig and their research staff will have access to your name and personal information. All of the forms that contain your name such as this consent form, the

authorization to share personal information, and your address and phone number will be kept in a locked office in a locked file cabinet at UIC separate from other research documents. All blood and rectal swabs will be labeled with your unique study ID and kept frozen in a locked laboratory at the UIC College of Medicine until analysis.

Electronic research records will be managed using the Research Electronic Data Capture system (RedCap), a password protected, secure web-based database application. Your electronic research record will not include your name but your unique study ID number only. Only research staff members have access to your electronic research record.

Results of this study may be used for teaching, research, publications, or presentations at scientific meetings**.** If your individual results are discussed, your identity will be protected by using a unique study ID number rather than your name or other identifying information. When the results of the research are published or discussed in conferences, no information will be included that would identify you personally.

All research materials will be held in the strictest confidence indefinitely or until the study is terminated, at which point all research materials, including blood and rectal swabs will be destroyed or properly discarded.

Will health information about you be created, used or shared with others during this study?

State and federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require investigators to protect your health information. By signing this form, you are also authorizing Dr. Mary Dawn Koenig and their research team to use the health information provided by you for the purposes of this research. This includes the information as described within this form and specifically includes demographic information (i.e., name, age, and race), height, weight, medical history and medications used.

During the conduct of the research, the investigators may use or share your health information:

- With other research staff involved with the study;
- With law enforcement or other agencies, when required by law; and
- With representatives of government agencies, review boards including the University of Illinois at Chicago Institutional Review Board, the University of Illinois Medical Center and its representatives, and other persons who watch over the safety, effectiveness, and conduct of research.

This authorization does not have an expiration, but you may withdraw your permission for the use of your health information for this study at any time by sending a letter to the principal investigator: Dr. Mary Dawn Koenig, 845 S. Damen Ave Room 814, Chicago, IL 60612. If you cancel this authorization, the investigators may still use and disclose the health information they have already obtained as necessary to maintain the integrity and reliability of the research.

If all information that identifies you is removed from the health information, the remaining information is no longer subject to the limits of this Authorization or to the HIPAA privacy laws.

Therefore, the de-identified information may be used and released by the researchers (as permitted by law) for other purposes, such as other research projects.

How will your health information be protected?
The researchers agree to protect your health information and will only share this information as described within this research consent/authorization form.

When your health information is given to people outside of the research study, those agencies that receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it. They may also share your information with others without your permission, if permitted by laws that they have to follow.

What if I am injured as a result of my participation?
If you believe that you have become ill or been injured from taking part in this study, treatment may be obtained through:

- The University of Illinois Health and Hospital System OR
- Your regular doctor OR
- The treatment center or clinic of your choice.

If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

You may contact the researcher Mary Dawn Koenig at (312) 996-7942 to talk about your illness or injury.

You or your insurance company will be billed for this medical care. Your insurance company may not pay for some or all of this medical care because you are participating in a research study. There are no plans for the University to provide free medical care or to pay for research-related illnesses or injuries, or for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries.

By signing this form you will not give up any legal rights.

What are the costs for participating in this research?
There are no costs to you for participating in this research. The study will provide the vitamin and probiotic supplements, research-related blood draws, and all research–related testing at no cost to you or your insurance. All other standard of care pre-natal and obstetrical visits (not related to this research) will be billed to your insurance provider or to you if you don't have insurance.

Will I be reimbursed for any of my expenses or paid for my participation in this research?

You will receive cash for each completed study visit. If you do not finish the study, you will be compensated only for the visits you have completed. If you complete all parts of the study, you will receive a total of $199 in cash. You will receive your payment immediately after each completed study visit. At baseline you will receive $70 cash for completing the study visit. At the 24-28 and 34-36 week visits you will receive $50 cash after completing the visit. You will receive $29 cash and one pack each of diapers and wipes at the labor and delivery data collection visit. You will receive one pack each of diapers and wipes for each of the 4 pill pick up visits.

Can I withdraw or be removed from the study?

If you decide to participate, **you are free to withdraw your consent and discontinue participation at any time** without affecting your future care at UIC. Your Authorization for release of health information for this research study *does not have an expiration date* but can be canceled sooner if you decide to withdraw your permission.

You may change your mind and cancel this Authorization at any time. To cancel this Authorization, you must write to: Dr. Mary Dawn Koenig, 845 S. Damen Ave., Room 814, Chicago, IL 60612. If you cancel this Authorization, you may no longer be allowed to take part in the research study. Even if you cancel this Authorization, the researchers may still use and disclose health information they have already obtained as necessary to maintain the integrity and reliability of the research and to report any adverse (bad) effects that may have happened to you.

You have the right to leave a study at any time without penalty. For your safety, however, you should consider the investigator's advice about how to leave the study. If you leave the study before the final planned study visit, the investigator may ask you to complete the final steps.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You were to object to any future changes that may be made in the study plan; or
- If you do not follow the study procedures.

In the event you withdraw or are asked to leave the study, you will still be compensated as described above for what you have completed.

What if I am a UIC student?

You may choose not to participate or to stop your participation in this research at any time. This will not affect your class standing or grades at UIC. The investigator may also end your participation in the research. If this happens, your class standing or grades will not be affected. You will not be offered or receive any special consideration if you participate in this research.

What if I am a UIC employee?

Your participation in this research is in no way a part of your university duties, and your refusal to participate will not, in any way, affect your employment with the university, or the benefits, privileges, or opportunities associated with your employment at UIC. You will not be offered or receive any special consideration if you participate in this research.

Photography Consent

Below you can consent to be photographed by members of the University of Illinois at Chicago research team. We will photograph you completing study related tasks, and your face will be included in these photographs. Your name will not be included with the photographs. These photos may be used for research purposes only, including presentations and posters at scientific conferences.

☐ I agree to have my photographs taken and used for research purposes.
Initials _____

☐ I DECLINE to have my photographs taken and used for research purposes.
Initials _____

Remember:

Your participation in this research study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Right to Refuse to Sign this Consent/Authorization.

You do not have to sign this Consent/Authorization. However, because your health information is required for research participation, you cannot be in this research study if you do not sign this form. If you decide not to sign this Consent/Authorization form, it will only mean you cannot take part in this research. Not signing this form will not affect your non-research related treatment, payment or enrollment in any health plans or your eligibility for other medical benefits.

Signature of Subject.

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research and authorize the researchers to use and share my health information for research. I will be given a copy of this signed and dated form.

_____ _____

Signature Date

_____

Printed Name

I have discussed the above research study, including the purpose, procedures, risks, and benefits, with the subject. I encouraged questions and answered all questions that were asked. The subject is aware that he/she does not have to participate in the research and may later withdraw their Authorization.

_____ _____ _____

Signature of Person obtaining consent Date Printed Name