ORAL PROBIOTIC SUPPLEMENTATION IN PREGNANCY TO REDUCE GROUP B STREPTOCOCCUS COLONIZATION (OPSiP)

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Sponsors: The Alva Foundation

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Emergency Telephone Number 604-652-8084

Invitation

You are being invited to take part in this research study because you are a healthy individual over the age of 18, pregnant with one baby and are currently less than 25 weeks along in your pregnancy. You are also under the care of a regulated maternity care provider (registered midwife, family doctor or obstetrician) and you are registered at either St. Paul's Hospital or BC Women's Hospital in Vancouver, British Columbia, planning either a hospital or out of hospital birth.

Your participation is voluntary

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving.

You should be aware that there is a difference for both you and your maternity care provider between being a patient/client and being a research participant. As a patient/client all medical procedures and treatments are carried out for your benefit only according to standard accepted practice. As a research participant you and your care provider also must take into account the requirements for the research study. These may include procedures and treatments that are not part of standard practice or are not yet proven. This consent form describes the diagnostic and treatment procedures that are being carried out for research purposes. Please review the consent document carefully when deciding whether or not you wish to be part of the research and sign this consent only if you accept being a research participant.

If you wish to participate in this study, you will be asked to sign this consent form.

Please take time to read the following information carefully and to discuss it with your family, friends, and care provider before you decide.

Who is conducting this study?

This study is sponsored through a research grant awarded to the University of British Columbia and the study investigators by the Alva Foundation located in Toronto, Ontario. This research is being completed as part of study investigator Kelly Hayes postgraduate research degree at Dublin City University. The supplements used as part of this study have been donated by Blis Technologies, New Zealand, and Chr. Hansen, Denmark.

Background

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Group B streptococcus (GBS) is a type of bacteria that can be found in many parts of the human body (colonizes), including in the vagina and rectum (bottom). GBS is a "transient bacteria", meaning it can come and go; one month you may have GBS in your body, and the next month it may be gone. You generally don't know it's there as it rarely causes any harm in healthy adults. However, if you have GBS in your vagina or rectum at the time you go into labour it can be passed to your baby and sometimes, but rarely, will make the baby very ill. If this happens it is called "early onset GBS infection" or "EOGBS" and will cause the baby to get sick within the first 7 days of life. EOGBS in the newborn can cause infections such as pneumonia. In rare cases EOGBS infection in newborns can cause death.

To reduce the risk of EOGBS in your newborn, your care provider will offer you a test in the form of a swab, which is like a long Q-tip, to check if you have GBS. This test is usually done between 35 to 37 weeks of pregnancy. Up to 30% of individuals will test positive for GBS, meaning they do have it. 50% (half) of babies born to these individuals will get GBS bacteria on or in them (colonized). This in itself causes no symptoms or problems for 98-99% of babies. However, the other 1-2% of babies who get colonized by GBS may become ill with early onset GBS infections.

Luckily, GBS infection is rare. The number of babies that get ill from EOGBS has dropped from 1-2 in every 1,000 births, or 0.01-0.02%, in the 1990's to 0.35-0.5 in every 1,000 births now, or 0.035-0.005%.

Although the risk of EOGBS infection is very rare, some babies do die if they get it. The number of babies that die from EOGBS infection has dropped significantly, from 70% of those who got sick from EOGBS in the 1990's to less than 3% now.

If your routine swab result is positive for GBS (meaning you do have it), in order to reduce the risk of your baby getting ill from GBS, it will be recommended that you receive intravenous (IV) antibiotics during your labour and delivery, usually penicillin. However, if your routine swab is negative for GBS (meaning you do not have it) then it would not be recommended for you to have IV antibiotics for GBS (although you might be recommended to have them for other reasons). This is what is called "the standard of care" for all pregnant individuals in Canada. If you choose to participate in this study, ***the standard of care will not change***.

Currently there is no recommended standard of care for preventing or reducing the chance of GBS colonization in pregnancy.

What are probiotics?

Probiotics are live micro-organisms or "good bacteria", that when eaten, may provide health benefits. There are many types of probiotics. The probiotics that have been chosen for this study are *Lactobacillus rhamnosus*, *Lactobaciluus reuteri* and *Streptococcus salivarius*.

The lactobacilli, when taken by mouth, will settle in the digestive tract (gut) and in the vagina. If the right amount is taken than they can replace some disease-causing bacteria and reduce the chance of certain infections, such as vaginal yeast infections. Pilot studies in

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pregnant individuals have also shown that these lactobacillus probiotics may reduce or stop GBS bacteria from settling in the vagina.

Streptococcus salivarius has been widely and safely used in both chewing gum and lozenge form to reduce strep throat infections (Strep A) in both adults and children. The focus of this particular probiotic has been on mouth and throat health, however, studies done in laboratories have shown that S. salivarius has the ability to both stop the growth of and kill GBS bacteria.

Are probiotics safe to take in pregnancy?

Probiotics are considered safe and their use may result in positive health benefits; however, a study utilising these three specific species of probiotics has not been done in relation to GBS in pregnancy. The College of Family Physicians of Canada has concluded that probiotics are generally considered safe and are well tolerated in pregnancy. The most common negative side effect of probiotics is flatulence (increased gas), which usually resolves with continued use of the probiotic.

Some studies have shown that in people who are severely immune-compromised there may be risk of less than 1 in 1 million of the probiotics themselves causing an infection; even though the risk is very minimal, if you are immune-compromised (for example, you are a cancer patient or you are on immune therapy treatment) then you would not be eligible for this study (see below for eligibility).

Health Canada has approved each of the three probiotics that will be used in this trial for use in the general population, including adults and children. Health Canada approval was also received specifically for this study. The *lactobacillus* probiotics have been used many times in studies involving pregnant women. The *S. salivarius* probiotic has, to date, mostly been used to investigate its ability to improve oral health and thus has not had the same degree of testing specifically with pregnant individuals. However, a small (yet to be published) study in New Zealand with pregnant individuals did not find any concerns for them or their babies.

What is the purpose of this study?

The purpose of this study is to test whether the use of three specific probiotics taken daily by mouth (oral) from 25 weeks of pregnancy until delivery can reduce the number of individuals who test positive for GBS (are colonized) at the time of their routine GBS swab, which is usually done between 35-37 weeks of pregnancy.

If these probiotics *do* have the ability to reduce GBS colonization, then it would also mean that fewer individuals would receive IV antibiotics in labour for GBS. Safe, preventative care to reduce infections and hence antibiotic exposure is important because of a growing concern over the high use of antibiotics and their potential for certain side effects and/or complications.

The other aims of this study are to determine whether these probiotics show an ability to reduce urinary tract infections and vaginal infections in pregnancy.

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If an individual does have GBS at the time they go into labour and/or if they end up with certain urinary tract or vaginal infections in pregnancy, antibiotics have an important role in lessening the chance of certain bad outcomes, such as a baby getting sick from GBS.

This study is looking at a way to *prevent* (or lessen) the chance of individuals being colonized with GBS in the first place and/or of getting urinary tract or vaginal infections in pregnancy.

This is a Phase III study. A Phase III study is a study of an experimental drug or treatment which is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information to determine whether the experimental drug or treatment can be used safely.

Who can participate in this study?

You may be able to participate in this study if*:*

- You are healthy and pregnant with one baby
- You are currently less than 25 weeks pregnant
- You are over the age of 18
- You are pre-registered, and intend to remain so until delivery, at either St. Paul's Hospital or BC Women's Hospital (planned home birth included)
- You are under the care of a regulated maternity care provider (Midwife, Obstetrician or Family Doctor)

Who should not participate in this study?

You will not be eligible to participate in this study if:

- You are unable or choose not to provide consent
- You or your baby have a serious medical condition or are immune compromised (please feel free to discuss in case you may be eligible)
- You are enrolled in another study that involves the administration of a drug or product (this could also interfere with finding out if the study's supplements are effective or not and/or vice-versa for other studies)
- You had a prior baby diagnosed with a GBS infection (you will automatically be recommended to receive IV antibiotics in labour regardless of your GBS status.)
- You have been diagnosed in this pregnancy with a GBS urinary tract infection (called GBS bacteruria) (you will be recommended to receive IV antibiotics in labour regardless of your GBS status).

*Please note: For those with dietary conditions the lozenge is *not* dairy free*

What does this study involve?

This is a double-blind, randomized, placebo controlled trial. This means that participants, through a computerized system, will be "randomly" assigned (think of tossing a coin) to take either the probiotics or the placebos. The placebos will look, smell and taste exactly like the probiotics but they won't have any active ingredients in them. Double-blind means that neither you, nor your maternity care provider or the researchers will know if you are taking

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the probiotic or the placebo. However, this information can be made available to your care providers in the case of an emergency. If you choose, at the end of the study you can find out if you were taking the placebo or the probiotic.

We will enrol 450 healthy pregnant individuals and expect the study to take three years to complete. The study will investigate whether *L. rhamnosus, L. reuteri* and *S. salivarius*, when combined and taken daily, can reduce GBS colonization in pregnant individuals based on the result of your last study GBS swab, most likely obtained between 35-37 weeks of pregnancy. We will also keep track to see if there are certain additional positive effects, such as improved mood and/or a reduction in urinary and vaginal infections, as well as keep track of and any negative side effects, such as flatulence.

If I participate will my care be different than for pregnant individuals who are not participating?

You will be offered and receive all the same testing, recommendations and physical care that a pregnant individual not participating in this study would receive from their care provider.

However, participation in this study does entail some *additional* things outside of your regular maternity care.

They include:

1) Attending an intake visit

Time: Approximately 20-45 minutes

This visit will take place at the Vancouver study site of your choice. During this visit one of the researchers involved in the study will go over all of the study details, make sure you are eligible and give you time to ask any questions that you may have regarding your participation.

If you choose to participate you will be asked to sign this consent form and then you will be randomized to either the probiotic or placebo group.

You will then receive a package of information that will include study specific instructions, study contact information and your own unique study ID number.

You will have a choice of filling out study questionnaires on paper (hard copy) or doing them on-line through a confidential system called “RedCap”. If you choose to use hard copy, we will give you self addressed, pre-stamped envelopes and/or you will be able to drop them back off at a study site. If you choose on-line forms, we will set this up for you and show you how to complete them..

You will be given your first batch of study supplements.

The capsules are vegan and gluten free. Each probiotic capsule contains 2.5 billion CFU (colony forming units) each of *Lactobacillus reuteri* and *Lactobacillus rhamnosus*. Other ingredients (for culture and capsule case) are maltodextrin, microcrystalline cellulose, magnesium stearate, hypromellose, and titanium dioxide. The placebo contains the the same ingredients with the addition of a non-medicinal ingredient, Silicone dioxide, and

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with no lactobacillus probiotics.

The lozenges are vegetarian (contains dairy) and gluten free. Each probiotic lozenge contains 2.5 billion CFU of *Streptococcus salivarius*. Other ingredients are isomalt, Silicified microcrystalline cellulose and magnesium sterate (tableting aids) and natural flavor. The placebo contains the exact same ingredients but without the *S. salivarius* probiotic.

The bottles containing each of the products will be given to you in a ziplock bag with a label that has your study ID number on it.

At this visit we will collect the first of three study vaginal ~~GBS~~ swabs, which you may choose to do yourself while there (we will tell you how and will also give you written instructions) or you may choose to have a clinician do the swab for you.

Oral (mouth) swab: At that visit we will also ask you to do an oral (mouth) swab. This swab will be analyzed to find out if you and how many other participants had GBS bacteria in their mouth. This swab and the information we learn from it will not impact you or your pregnancy in any manner; it is simply to help us gain a better understanding of where GBS is located in the body.

You will be given written instructions on how to store and take your supplements and we will discuss with you things you can do that may help remind you to take them

2) Taking the supplements from 25 weeks until you deliver your baby

When? Daily

Your daily supplements (either the probiotics or the placebos) will include 2 capsules to be taken at any time of the day and 1 peppermint lozenge to be slowly sucked at night after you've brushed your teeth before bed.

If you are on antibiotic(s), during the course of your participation then you are advised to take your supplements at least 2-3 hours before or after taking your antibiotics.

Taking you supplements every day is very important! This is how we will find out if these probiotics are helpful in reducing the chance of having GBS. Previous studies that looked at the lactobacillus probiotics showed that individuals who took them regularly were more likely *not* to have GBS than those who tended to miss days.

3) Filling out three (3) questionnaires (on-line or hard copy)

When? **One:** *Before* starting you study supplements

Two: Between 29 weeks and 33 weeks of pregnancy (mid-point)

Three: Between 4 to 6 weeks *after* having your baby

Time: Approximately 10 minutes each

All the questionnaires are confidential and only include your study ID number for identification (they will not have your name, contact numbers or address on them).

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The questionnaires have a combination of check boxes and written answers. We encourage you to answer all the questions, but you do have the right to decline. If at any time you are unsure what a question means or have a concern about any of them, you will be able to contact us for help or discussion.

Information from the questionnaires is used as "data" to help us put different pieces of the study questions and their conclusions together. For example, we ask about certain questions about lifestyle, such as what your diet is like and what kind of emotional support you have. In research, these types of answers help us to figure out what other things might influence (or effect) the study results and/or make something work better or worse.

Questions on the first questionnaire include things like your age, your ethnicity, the types of food you eat, and information about previous pregnancies and your current pregnancy. On the second and third questionnaires we ask about things that have happened since the last study questionnaire you did, like any infections you may have been diagnosed with, whether you needed antibiotics, and if and when you delivered your baby.

4) One phone-call check-in (more if requested)

When? 2 weeks after the start of your participation (@27 weeks of pregnancy)

Time: 2-3 minutes or longer if you need

A member of the study team will contact you at your preferred number and day of week/time to check in and see how you are doing with taking your supplements. This will be a good opportunity for you to ask any questions or voice any concerns.

Note: There will be a study team member available throughout your participation. You can contact us at **any point during your participation if you have questions or concerns. Any communication you have with us will be kept on a communication log with your study ID number and will be held confidential.*

5) Three vaginal swabs and two oral swabs (5 swabs total):

**Note: You will still do your "routine" vaginal GBS swab with your maternity care provider after 35 weeks of pregnancy.*

When? **First vaginal and first oral swab:** At your intake visit

Second vaginal swab: Between 29 and 33 weeks of your pregnancy (will be obtained at your mid-point visit (see below).

Third vaginal and second oral swab: Between 35 weeks and delivery. To be done at or around the same time as your standard GBS swab.

Time: Actual swab 2-3 minutes

Drop off for last swabs: Dependent on the study site location that you choose.

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You will be given your last swabs and their requisition forms at your mid-point visit. You have the choice to either complete the swabs yourself or arrange to have a clinician do the swabs for you.

The study vaginal swabs are done exactly the same way that your routine GBS swab will be done after 35 weeks and involve placing the swab, which is similar to a long Q-tip, just inside your vagina and then the tip just inside your rectum (bottom). Full instructions will be provided to you at your intake visit and are also available on-line at www.opsipstudy.com.

For your last study swabs (one oral and one vaginal to be done *after* 35 weeks of pregnancy) you will need to make sure to drop them off within 1 to 2 hours of doing them to one of the study sites for collection. *We recommend doing the swabs just prior or shortly before leaving for drop off.

5) Mid-point check-in with supplement pick up

When? 29-33 weeks of pregnancy

Time: 10-15 minutes

You will need to book this appointment ahead of time at the study site of your choice. To do so, please call 604-875-2000 extension 4886..

At this appointment you will meet with a study team member.

We ask you to bring any empty packaging from the supplements you received at your intake visit (keep any bottles that have remaining supplements as you will continue taking them). You will then be given your next and final batch of supplements. As before, they will be given to you in a zip-lock bag and we ask that you put your supplements into the fridge until you are ready to start a new bottle.

At this appointment you or a clinician will do your second vaginal swab. If you'd like a clinician to do the swab please let us know at the time you book your appointment.

Use of Data from Secondary Data Sources

By consenting to participate, it also means you are giving consent for your and your newborn's medical chart to be reviewed to obtain study data, for example, how many weeks pregnant you are when you go into labour, the laboratory results of swabs taken, the names and doses of any medications or antibiotics prescribed during your pregnancy. All study data, including from your questionnaires, will be entered using your unique study ID number and will not have personal identifiers on it, for example your name or address. All information collected will be kept confidential.

If you deliver your baby outside of hospital, we will ask for you to consent for us to contact your primary care provider to access your medical records for review.

You will also be given the opportunity to consent to be contacted for future research. For example, we hope to follow up with the babies born during this study and collect data on

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any antibiotic exposure and subsequent childhood diseases. Giving consent would only be for us to contact you – any future study would have its own individual consent process.

What are my responsibilities?

We kindly ask that participants do not take other probiotic supplements, either by mouth or inserted in the vagina, during participation in this study. Although this won't be a reason to withdraw you from the study once you have enrolled, it will make it difficult for us to know which probiotic (if any) has been helpful.

Also, because the study sites and labs we are using and approvals for running the study are based in Vancouver, we ask that if you *know* you will be moving from the lower mainland prior to having your baby that you do not enrol in this study.

What are the possible harms and discomforts?

Outside of the possibility of some increased flatulence and/or bloating, we are not anticipating that you will experience negative side effects related to the study supplements. However, if you choose to participate and you do have a negative side effect that you feel might be from the study supplements, then there are several ways that you will be able to alert the study team, including by phone or email.

The risks and side-effects of the standard or usual treatment of GBS will be explained to you as part of your standard care with you maternity care provider.

What are the potential benefits of participating?

No one knows whether or not you will directly benefit from this study. However, if you are randomized to the probiotic arm you could benefit from improved health, such as improved mood, improved gastrointestinal health and a decreased risk of certain vaginal infections.

The majority of women who participate in studies in pregnancy have a positive experience. By participating you will help us learn if we can reduce the negative impact GBS has on both mothers and babies through preventative therapy with probiotics. We hope that the information learned from this study can be used in the future to benefit other pregnant women and their babies.

What are the alternatives to the study treatment?

There are currently no standard preventative treatments that are recommended in pregnancy to reduce GBS colonization. There are some alternative treatments that your care provider may discuss with you or that you might hear or read about that *may* have the potential to impact GBS, such as probiotics, but to date there haven't been studies big enough or focused enough to show that they have definite benefit and if so, to what degree.

What if new information becomes available that may affect my decision to participate?

If you choose to enter this study and at a later date an effective treatment does become available, it will be discussed with you. You will also be advised of any new information that becomes available that may affect your willingness to remain in this study.

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What happens if I decide to withdraw my consent to participate?

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, all information about you collected up to the point of your withdrawal [including, where applicable, information obtained from your GBS swabs] will be retained for analysis in order to protect the integrity of the research, which may benefit future research participants and patients/clients. However, no further information will be collected.

Can I be asked to leave the study?

If you are not able to follow the requirements of the study or for other reasons, the study co-ordinator or a study investigator may withdraw you from the study. For example, if for some reason you end up needing immune suppressant therapy we would need to withdraw you from the study.

Withdrawing from the study, no matter the reason, would not impact your standard maternity care with your care provider. If you are asked to leave the study, the reasons for this will be explained to you and you will have the opportunity to ask questions about this decision.

How will my taking part in this study be kept confidential?

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or their designate by representatives of Health Canada, and the UBC Research Ethics Board for the purpose of monitoring this research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

If you consent to take part in this study, your medical records pertaining to your pregnancy, labour and delivery and postpartum care and your newborn's records if applicable, will be reviewed at the end of your participation by the investigators or the study-coordinator for the purposes of analyzing the results.

You will be assigned a unique study ID number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. The swabs collected as part of this study will have your month and year of birth, as required by the laboratory, but no other identifiers beyond your study ID will be included. Data in the electronic system will be stored under study ID numbers only.

All hard copy data will be stored in the Clinical Support Building at BC Women's and Children's Hospital. Records will be securely stored and will be kept for 25 years. The investigators will be responsible for their safekeeping. Only the study team will have access to raw data and clinical information relating to the study, and they will hold and maintain the confidentiality of the code linking participant identifiers to the study ID. A de-identified

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and aggregated copy of the study data used for analysis may be made available as part of the final study publication, according to medical journal requirements.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. You also have the legal right of access to the information about you, and if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study coordinator.

Will my Primary maternity care provider (midwife, family doctor or obstetrician) be told I am in the study?

At your intake visit, you will receive a letter to be given to your maternity care provider so that they are aware of your participation, or if you prefer, we can send it to them for you.

It is always good (and is advised) to let your care provider know what medications, vitamins and/or natural supplements or remedies you are taking. This letter will inform them of the study products and will provide study contact information.

Please indicate, by checking the applicable box, whether you want us to notify your primary care physician(s) or specialist(s) of your participation in this study. This is not a consent to release medical information.

☐ Yes, I want the study investigator to advise my primary care provider(s) of my participation in this study.

☐ Yes, I consent to the study investigator contacting my primary care provider(s) to access my medical records in their office, in the event that I deliver my baby at home.

My primary care provider(S) is/are: _____

The name of the medical clinic I attend is: _____

Participant Initials: _____

☐ No, I do not want my primary care provider(s) made aware of my participation in this study.

Participant Initials: _____

☐ The study investigator is my primary care physician/specialist.

Participant Initials: _____

I understand that if I choose not to advise my primary care provider or specialist(s) of my participation in this study there may be potential medical consequences that may affect my comprehensive medical care or treatment. I understand that the study investigators may not be responsible for these consequences. You may wish to discuss the consequences of your decision with the study staff.

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Disclosure of Race/Ethnicity

Studies involving humans now routinely collect information on race and ethnic origin as well as other characteristics of individuals because these characteristics may influence how people respond to different medications or health products. Providing information on your race or ethnic origin is voluntary and is located on the first questionnaire and in your medical records.

What happens if something goes wrong?

By signing this form, you do not give up any of your legal rights and you do not release the researchers, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan.

In case of a serious medical event, please report to an emergency room and inform them that you are participating in a clinical study and that the following person can then be contacted for further information: Kelly Hayes (or another study team member) at telephone number: **604-652-8084**

You will be given a wallet sized Study Card at intake and is recommended you carry it with you. This card can be shown or given to any health care provider to alert them of your participation and it will include the study emergency contact number.

What will the study cost me?

All research-related capsules and lozenges and any related tests that you will receive during your participation in this study will be provided at no cost to you.

We don't expect you to incur any study related costs. However, if you do incur costs, (ie. parking) the study is not in a position to reimburse you.

Who do I contact if I have questions about the study during my participation?

If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact a study team member at 604-875-2000 extension 4886.

Although not anticipated, in the event of a research related injury, please speak to your primary maternity care provider or (after hours) report to an emergency room.

Who do I contact if I have any questions or concerns about my rights as a participant?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598). Please quote the study id H17-02189 on any communication with the complaint line.

After the study is finished

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If after the study is completed you would like to know the results and whether you received the probiotics or the placebos, we would be happy to send you both a summary of the study and what your supplement allocation was.

Please provide your email address below if you wish to receive this information at the completion of the study:

_____

Thank you for taking the time to review this information and for considering participation in this study. If you have any questions or concerns about this study, please feel free to contact the investigators or the study coordinator.

Future Contact

I consent to the investigators of this study contacting me for future research.

☐ Yes

☐ No

If yes, please fill in a primary AND alternate way of contacting you (ie. email, phone, address)

1. _____

2._____

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Signatures

"Oral probiotic supplementation in pregnancy to reduce group b streptococcus colonization at term (OPSiP)"

Participant Consent

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
- I authorize access to my health records relating to my prenatal, delivery and postnatal care, as described in this consent form.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me.

I will receive a signed copy of this consent form for my own records.

I consent to participate in this study.

Participant's Signature	Printed name	Date

Signature of Person Obtaining Consent	Printed name	Study Role	Date

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If this consent process has been done in a language other than that on this written form, with the assistance of an interpreter/translator, indicate:

Language: _____

Was the participant assisted during the consent process in one of ways listed below?

☐ Yes ☐ No [Note: For typical situations where the person conducting the consent discussion simply reads the consent with the participant to ensure that informed consent is properly obtained, check "no".]

If yes, please check the relevant box and complete the signature space below:

☐ The consent form was read to the participant, and the person signing below attests that the study was accurately explained to, and apparently understood by, the participant (please check if participant is unable to read).

☐ The person signing below acted as an interpreter/translator for the participant, during the consent process (please check if an interpreter/translator assisted during the consent process).

_____	_____	_____
Signature of Person Assisting in the Consent Discussion	Printed Name	Date

Investigator Signature

_____	_____	_____
Investigator Signature	Printed name	Date

My signature above signifies that the study has been reviewed with the study participant by me and/or by my delegated staff. My signature may have been added at a later date, as I may not have been present at the time the participant's signature was obtained.

SAMPLE