Informed Consent Form for Participation in a Research Study

Study Title: Elucidating the Dynamics and Impact of the Gut Microbiome on Maternal Nutritional Status During Pregnancy (MMIP Study)

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INTRODUCTION

You are being invited to participate in a research study. You are invited to participate in this study because you are 24 years of age or younger, living in Toronto and you have recently become pregnant. This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision. You may find it helpful to discuss it with your friends and family.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that you receive outside the study.

IS THERE A CONFLICT OF INTEREST?

There are no conflicts of interest to declare related to this study.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to examine a mother's nutritional status and her gut microbiome, so that we can learn more about the relationship between the two during pregnancy, and how they contribute to the birth outcome and health of her baby.

In your gut, there are different organisms called microbes, which include bacteria, viruses, and other microbes. Together, these are called the gut microbiome. The gut microbiome is very important to your body's ability to function and maintain good health. It can also help you digest food and absorb nutrients so it affects your nutritional status. Sometimes when we get sick or are exposed to different elements such as medication or types of food, the good microbes that promote good health decrease or die, while the number of potentially harmful microbes increase.

Undernutrition is a condition characterized by poor nutritional status such as low weight, poor growth or nutrient deficiencies and can be caused by eating too little food, or consuming foods that do not have enough vitamins and minerals to support good health. Research has found that the gut microbiome can also affect whether someone has undernutrition. During pregnancy, it is very important that a mother consumes enough healthy foods to nourish both the mother and the growing baby. The microbiome is important during pregnancy, too, given its role in maintaining good health and nutrition. Few studies have examined the role of the microbiome on measures of health and nutritional status of both the mother and the baby. As well, little is known about how microbes in the gut can influence a mother's nutritional status.

In this study, we want to examine the relationship between your nutritional status during pregnancy and the gut microbiome, and how they contribute to your health status during and after pregnancy, birth outcomes and the health status of your baby during the first year of life.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about 400 pregnant women and their babies will take part in this study, from research sites located in the Greater Toronto Area, with an additional 400 women and their babies recruited from a similar cohort in Pakistan.

This study should take about 5.5 years to complete and the results should be known in about 7.5 years.

WHAT WILL HAPPEN DURING THIS STUDY?

	Visit 1: Baseline	Visit 2: 30-34 weeks Post-Conception	Visit 3: 4 Months Post-Partum	Check in Call: 8 Months Post-Partum	Visit 5: 12 Months Post-Partum
Screening and informed consent (30 minutes)	X				
Maternal Anthropometric Measurements (~10 minutes)	X	X	X		X
Baby			X		X

Anthropometric Measurements (~10 minutes)					
Maternal Questionnaires (~20 minutes)	X	X	X	X	X
Baby Questionnaires (~20 minutes)			X	X	X
Maternal Stool sample (10 minutes)	X	X	X		X
Baby Stool Sample (10 minutes)			X		X
Maternal Rectal swab (10 minutes)	X	X	X		X
Baby Rectal Swab (10 minutes)			X		X
Maternal Blood Sample (10 minutes)	X	X			X
Baby Blood Sample (10 minutes)					X
Maternal Dietary Recall #1 (30 minutes)	X	X			X
Maternal Dietary Recall #2 (3-10 days later) *This will take place over the phone.*	X	X			X

Screening: Screening will be performed first to determine if you are eligible to take part in the study. The research member will ask you a few questions about your medication use, age and weight/ height. This screening questionnaire will take about 2-5 minutes to complete and it can be done over the phone or in person. The research member may check your medication use, age and/ or height and weight from your chart to determine whether you are eligible to participate.

Study Visits: If you consent to join the study it will involve four study visits; the first will take place between 8-20 weeks post-conception, the second visit will take place between 30-34 weeks post-conception, the third visit will take place around 4 months post-delivery and the final visit will take place around 12 months post-delivery. We will aim to schedule your visits at the same time as your clinic visits, so that you won't need any extra visits to the hospital. The two visits post-delivery will also include your baby as a study participant.

Questionnaires: During the study visits you will be provided with questionnaires, the information collected will be dependent on the study visit. Each questionnaire will take between 5-15 minutes to complete. The purpose of the questionnaires are:

- To assess your health status, with questions related to your medication use and illnesses
- To collect demographic information, with questions about your age, the number of pregnancies you've had, the number of children you have, the languages spoken in your home, your race/ ethnicity, immigration status, education, income, and housing
- To collect information about your birth history
- To assess your nutritional intake, with questions related to you and your infant's diet and feeding practices
- To assess your perceived self-efficacy, perceived social support, decision making, perceived stress in addition to socio-economic factors, including food and housing insecurity

The information you provide is for research purposes only. Some of the questions are personal. You can choose not to answer questions if you wish.

Even though you may have provided medical information on a questionnaire, these responses will not be reviewed by your physician/health care team - if you wish them to know this information please bring it to their attention.

Information about your body measurements, delivery outcome/ assessment, medication use and illnesses may be taken from your chart and your infant's chart, if available.

Dietary recall (ASA 24): The ASA24 is a tool to collect a dietary recall and will be completed online with the help of a member of the research team. The research team will provide you with the URL (link) to access the questionnaire and will give you a unique username and password to access the website to enter your answers. This questionnaire will ask you about the foods you have eaten during the past 24 hours. You will need to do this online questionnaire 2 times (3-10 days apart) at each of the following visits: baseline, 30-34 weeks post-conception and at 12 months post-partum.

The purpose of the recall is to record your diet because research has shown that human diet can change the composition of the gut microbiome. Each time you complete the ASA24, you are going to need around 30-45 minutes. A research member will assist you while you complete the dietary recall.

Anthropometric measurements: At each study visit we will measure your height, weight, mid upper arm circumference and triceps skinfold thickness. Once your infant is born we will measure their length, weight, head circumference, mid upper arm circumference and triceps skinfold thickness at each visit. If this information is already available from your clinical chart or your baby's clinical chart this information will be taken from there.

Blood Collection: Your blood samples will be examined for anemia, nutrient levels (minerals and vitamins) and general metabolites (protein components, fat components etc). Blood samples will be taken by inserting a needle into a vein in your arm. When possible we will take the blood sample at the same time as the bloodwork routinely needed during pregnancy to avoid an extra poke. We will collect 5ml of blood at 3 different visits from you; baseline, 30-34 weeks post-conception and 12 months post-delivery. We will collect 3 ml blood once from your infant, at the final 12 month visit. These blood samples will be sent to a laboratory at The SickKids Research Institute where they will be stored and examined. Your samples will be analyzed at both The SickKids Research Institute and the Metabolomics Innovation

Centre. Samples will be sent to collaborators outside of SickKids and Canada. Samples will not be sold.

Stool Sample Collection: A stool sample is needed to assess the gut microbiome. At each of the four study visits you will be asked to provide one stool sample of approximately 1 gram. At the two visits post-delivery, we will also collect a stool sample from your baby; if possible this sample will be taken from their diaper. The stool sample collection can be done at home. We will provide you with the stool sample collection system "DNA/RNA Shield Fecal Collection Tube" that includes all the materials you need to collect the sample including illustrated instructions. With this method, the stool samples can be preserved at room temperature. It also prevents the growth of microbes and makes samples non-infectious so they can be handled and shipped safely. Stool sample collection will take about 5-10 minutes to complete.

When you are ready to submit the sample, you can do any of the following:

- Contact a prepaid courier service to pick up the sample from your home. You will not be charged for this.
- Send your sample into the lab in a pre-labelled FEDex envelope. You will not be charged for this.
- Or, the study staff will send you the sample kit prior to your visit, and you can bring the sample in with you when coming to the clinic.

Your stool samples will be sent and stored at The SickKids Research Institute until analysis. Your stool sample will be analyzed at The SickKids Research Institute and the Metabolomics Innovation Centre. Samples will be sent to collaborators outside of SickKids and Canada. Samples will not be sold.

Rectal Swab: A rectal swab can also be used to assess the gut microbiome. At each of the four study visits you will be asked to take a rectal swab, detailed instructions and a kit will be provided to you. At the two visits post-delivery, if there is no soiled diaper, we will also collect a rectal swab from your baby. The samples can be taken in clinic by yourself. We will provide you with "the Floqswab rectal swab kit" that includes all the materials you need to collect the sample including illustrated instructions. The rectal swab will take about 5- 10 minutes to collect. Once you collect the rectal swab the research staff member will send it to The SickKids Research Institute where it will be stored. The rectal swab will be analyzed at The SickKids Research Institute and the Metabolomics Innovation Centre. Samples will be sent to collaborators outside of SickKids and Canada. Samples will not be sold.

If you are uncomfortable taking the rectal swab, you can opt out of this part of the study and still participate.

The material collected from the rectal swab and stool sample, will be studied to find different microbes, metabolites (fat components, protein components, etc) and markers of inflammation.

The collection of the stool samples and serum samples are a necessary part of this study. Samples will be used only for these purposes. The samples will not be sold.

Once these tests have been completed, any leftover samples will be returned to The SickKids Research Institute if needed or destroyed, unless you wish to give permission for other future research purposes, in which case you can sign the additional genetic section of this consent form.

How will the samples be identified?

To protect your identity, the information that will be on your samples will be limited to your study ID, the study visit number and the sample collection date and time.

Despite protections being in place, there is a risk of unintentional release of information. Due to technological advances in genetics, there may be a risk that the genetic information in the samples could be linked back to you.

Can I withdraw these samples?

If you no longer want your samples to be used in this research, you should tell the research coordinator Carolyn Spiegel-Feld (carolyn.spiegel-feld@sickkids.ca) or Graham Cromar (graham.cromar@sickkids.ca), who will ensure the samples are destroyed.

You can request withdrawal of your specimens until the researchers begin sample analysis, which is when the samples will be made anonymous. It won't be possible to return samples after this because the researchers will not know which sample is yours.

Telephone and email contact: You may also receive phone calls or email from the research team, the purpose of the calls will be to:

- Follow up with you with about the completion of study tasks
- To schedule a study visit
- To complete the ASA24 dietary recall over the phone

Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to participate in this study, you will be expected to:

- Tell the researcher and research staff about all of your current medical conditions.
- Tell study staff about your health since the last study visit.
- Tell study staff about all your prescription and non-prescription medications such as over-the-counter drugs, antibiotics, probiotics, laxatives, and supplements, including vitamins and herbal medications, naturopathic treatments.
- Tell study staff if you are thinking about participating in another research study.
- Ask your study team about anything that worries you.
- Tell the study staff if you change your mind about being in this study.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

Your participation on this study will last for about 17-19 months in duration. You will be followed from 8-20 weeks into your pregnancy, until 1 year post-delivery.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the research team. There is no penalty for withdrawing from the study, you can withdraw from the study at any time, both you and your baby(ies) will continue to receive standard care.

You may withdraw your permission to use information that was collected about you for this study at any time by letting the research team know. However, this would also mean that you withdraw from the study.

Information that was recorded before you withdrew will be used by the researchers for the purposes of the study, but no information will be collected after you withdraw your permission.

CAN PARTICIPATION IN THIS STUDY END EARLY?

Your participation on the study may be stopped early, and without your consent, for reasons such as:

- New information shows that the research is no longer in your best interest
- The research team decides to stop the study
- The research ethics board withdraw permission for this study to continue

If you are removed from this study, the research team will discuss the reasons with you.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

There is a possibility of pain, bruising, swelling or infection related to the blood draw. These discomforts are minimal and brief.

During the questionnaires and the interview, you may experience some anxiety, emotional and/or psychological distress due to the nature of the questions. You can skip questions, take a break or stop answering at any time.

If your responses indicate that there is a serious risk of harm to yourself or others, confidentiality will be broken in order to protect you or another person. If we feel that you are in need of urgent care as result of participating in this research study, we will intervene according to routine clinical care practices.

You may experience discomfort collecting the stool sample and rectal swab, research staff members will provide detailed instructions. However, if you feel uncomfortable you may opt out of collecting the rectal swab.

Despite protections being in place, there is a risk of unintentional release of information. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You may not receive direct benefit from participating in this study. We hope the information learned from this study will help other women who become pregnant and their babies.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the research team will only collect the information they need for this study.

Records identifying you at this center will be kept confidential and, to the extent permitted by the

applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) medical records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- The researcher and research members
- Representatives of the study sponsor, CIHR
- The research ethics board who oversees the ethical conduct of this study in Ontario
- This institution and affiliated sites, to oversee the conduct of research at this location

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your participant code, sex and date of birth.

The following organizations may also receive study data and study samples:

- The University of Alberta, Dalhousie, the NIH and The University of Toronto will be sent microbes isolated from your gut microbiome, they will use these samples to further investigate the relationship between the microbiome and nutritional status. The University of Alberta, the NIH and the University of Toronto have animal labs where they will further examine this relationship through mouse and swine models. To further examine the role of the human microbiota on pregnancy and nutritional status, your stool samples may be used in animal studies involving mice and pigs. In these studies, the bacteria in the stool sample are fed to the animals, effectively transplanting the microbiome from your gut to the gut of the animals. These are called fecal microbiome transplants and help us to analyze the role of the microbiome in health.
- The University of Calgary will assist our team with the statistical analysis of the microbiome samples, they will not have access to identifiable information, all of the information shared with them will be de-identified.
- Other research collaborators may be sent de-identified data. Data will not be sold.

This research study is collecting information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how the microbes in your gut interact with your nutritional status and infant birth outcomes. Providing information on your race or ethnic origin is required.

Research data will be sent to central repositories:
If you consent to genetic sequencing, your genetic data will be sent to and stored in a central repository (storage place), which are sometimes called data banks. These data banks will store your genetic information indefinitely and allow other researchers to access your data for more research studies.

If the results of this study are published, your identity will remain confidential. It is expected that the microbiome data will be de-identified and uploaded on the National Centre for Biotechnology

Information (NCBI). The NCBI facilitates the automated storage and analysis of databases for the research and medical community. In addition to publishing findings in open access journals, we will ensure all de-identified sequences and metabolomics datasets are deposited in appropriate public repositories. SOPs, pathogen samples and statistical methods developed through this project will be shared with the IMPACTT research core.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

A copy of the consent form that you sign to enter the study may be included in your health record/hospital chart.

Microbes isolated from your gut may be sent to the NIH to further investigate how they might impact their host. Any information and samples, sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be as strict as in Canada. However, all study data and samples, that are transferred outside of Canada will be coded (this means it will not contain your personal identifying information such as your name, address, medical health number or contact information). Any information will be transferred in compliance with all relevant Canadian privacy laws. By signing this consent form, you are consenting to the disclosure of your coded information to organizations located outside of Canada.

Online Surveys or Third Party Websites or Apps

The ASA24 is an online questionnaire that was developed by the U.S. National Cancer Institute (NCI) and adapted for use in Canada by the Food Directorate at Health Canada. NCI will not have any contact information or identifying information about your child. Please note that the online survey is hosted by a company named Westat, which stores survey data on servers located in the United States of America (USA). You will need to provide an email address to create an account. Your data collected for the ASA24 will not be shared with other researchers. The data may be subject to foreign laws such as the USA PATRIOT Act that allows authorities access to the records of internet service providers if needed.

WHAT IS THE COST TO PARTICIPANTS?

Participation in this study will not involve any additional costs to you or your private health care insurance.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

As a token of appreciation for the time and effort spent on the study, you will be given a grocery gift card after each study visit. You will receive $20 for the first and final study visits, as these visits will be longer in duration. For the 2 visits in between, you will receive a $10 grocery gift card for each visit.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you

would like to be informed of the results of this study, please contact the research team.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form you do not give up any of your legal rights against the researcher, CIHR or involved institutions for compensation, nor does this form relieve the researcher, CIHR or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT A RESEARCH PARTICIPANT?

During the study, the researchers may learn something about you that they didn't expect. For example, the researchers may find out that you have another medical condition.

If any new clinically important information about your health is obtained as a result of your participation in this study, you will be given the opportunity to decide whether you wish to be made aware of that information.

During this study we may create new tests, new medicines, or other things that may be worth some money. Although we may make money from these findings, we cannot give you any of this money now or in the future because you took part in this study.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to the research team, or the person who is in charge of the study at this institution. That person is: Dr. John Parkinson, the study researcher.

Dr. John Parkinson	416-813-5746
Name	Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. You may contact the SickKids Research Ethics Board, the Office of the Research Ethics Board at 416-813-8279 during business hours.

David Kenney	416-813-5718
Name	Telephone

SIGNATURES

- All of my questions have been answered,
- I understand the information within this informed consent form,
- I allow access to medical records and transfer of specimens and related personal health information as explained in this consent form,
- I do not give up any of my legal rights by signing this consent form,
- I understand that my family doctor/health care provider may be informed of study participation
- I agree to take part in this study.
- I agree that once my infant is born they will also become a participant in this study

_____	_____	_____
Signature of Participant/	PRINTED NAME	Date
_____	_____	_____
Signature of Person Conducting the Consent Discussion	PRINTED NAME & ROLE	Date

The following attestation must be provided if the participant is unable to read or requires an oral translation:

If the participant is assisted during the consent process, please check the relevant box and complete the signature space below:

☐ The person signing below acted as an interpreter, and attests that the study as set out in the consent form was accurately sight translated and/or interpreted, and that interpretation was provided on questions, responses and additional discussion arising from this process.

_____	_____	_____
PRINT NAME of Interpreter	Signature	Date

_____

Version date of this form: 15 March 2021

Language

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to the participant, and any questions have been answered.

_____	_____	_____
PRINT NAME of witness	Signature	Date

_____
Relationship to Participant

Please note: More information regarding the assistance provided during the consent process should be noted in the medical record for the participant if applicable, noting the role or relationship of the impartial witness.

Optional Components of the Study

Optional means that you may refuse to consent to this part of the study without affecting your participation in the main study. Please take your time to make your decision.

Optional Component: Future Genetic Research Consent

If you agree to this, blood samples from you and your child will be collected and stored for future genetic research, This future genetic research is optional. Your decision whether or not to participate will not affect your participation in the main study. In general, genetic research involves isolating your genes from your sample(s). Every person has their own unique set of genes, or "genome". Genes carry the information that helps to determine your characteristics. Genes are made up of DNA; between people, the DNA sequence of a gene can vary slightly. These differences in DNA sequence are called variants. These variants may or may not be harmful. Genes are passed down from parents to children, but sometimes genes can change between generations or because of other factors (e.g., environment). Genetic research may be done in the future on your blood samples to further investigate how the microbes in your gut interact with your genes and how they affect and interact with your infant's genes.

Even with protections in place, there is a risk that your information and your infant's information could be released by accident. Advances in technology could also increase the risk that your genetic samples and results could be linked back to you or your blood relatives. These results might contain information (e.g., an inherited genetic disease) that could result in problems for you or your relatives. There is no way to predict what effects such an information loss would have. You will be given the choice to find out about genetics testing results.

If you are a First Nations or an indigenous person who has contact with spiritual Elders, you may want to talk to them before you make a decision about this research study. Elders may have concerns about some research procedures including the future genetic testing.

If you consent to this future genetic research, we will store you and your infant's blood samples (Biobank) and in the future we will conduct whole genome sequencing. Within your blood samples, your genetic information (the information that instructs your body on how to grow, reproduce, develop and defines who you are), will be extracted and sequenced. Conducting whole genome sequencing will allow the researchers to better understand how your genes and your gut microbiome interact and contribute to your nutritional status and the birth outcomes of your baby. To do this test we will need to collect a blood sample from both you and your infant, if you agree to the future genetic testing, it will be conducted on the samples of blood we collect during your study visits, it will not involve an additional blood sample. The genetic information (DNA) will be stored and in the future may be shared with other laboratories outside of SickKids. Your samples will not be sold.

Biobanking involves the collection of your biological samples to store for future research use. A biobank is a type of facility that receives, stores, processes and distributes biological samples as well as data related to those samples. Biobanks provide scientists with access to the samples and study data to conduct other research. We would like to biobank your samples and your infant's samples and genetic information for future research. We don't know the type of studies will be done with your sample(s) in the future.

You should be aware that genetic information cannot be protected from disclosure by court order.

The potential psychological and social risks of participating and receiving genomic information are not fully known at this time. It may be upsetting to learn about genetic causes and medically actionable findings. Because parent(s) and children can share genetic variants, the discovery of harmful variants in your genome may lead to identifying the same variants in your family members' genome. It may be upsetting to learn that other members of your family share harmful genetic variants with you.

For this optional part of the study, you are able to consent to biobank the blood samples for future whole genome sequencing of either: 1) Both you and your infant's blood samples, 2) Only your blood samples or 3) Neither of your blood samples. Please initial your preference in the box below.

Below are options for participation. Please initial next to your preference(s).

Optional Genetic Research Consent	
_____ Initials	Yes, I consent to have my blood biobanked for future whole genome sequencing.
_____ Initials	No, I do not consent to have my blood biobanked for future whole genome sequencing.

Optional Genetic Research Consent for your Infant	
_____ Initials	Yes, I consent to have my infant's blood to be biobanked for future whole genome sequencing.
_____ Initials	No, I do not consent for my infant's blood to be biobanked for future whole genome sequencing.

Genomic Sequencing Data:
Genomic sequencing allows us to test a person's DNA and find variations in DNA sequence for thousands of their genes at the same time. Your genomic sequencing data is unique to you and will have important health information about you.

We would like your permission to use your de-identified and or anonymized genomic sequencing data in future research. Please initial next to your preference:

Future Research of Genomic Sequencings data about me:	
_____ Initials	Yes, in the event that future genetic testing is performed, you can use my de-identified and or anonymized whole genome sequencing data for future research purposes.
_____ Initials	No, in the event that future genetic testing is performed, you cannot use my de-identified and or anonymized whole genome sequencing data for future research purposes.

Future Research of Genomic Sequencings data about my infant:

Initials	Yes, in the event that future genetic testing is performed, you can use my infant's de-identified and or anonymized whole genome sequencing data for future research purposes.
Initials	No, in the event that future genetic testing is performed, you cannot use my infant's de-identified and or anonymized whole genome sequencing data for future research purposes.

What if the researchers discover something about me?

It is important that you understand that although we will be examining your entire genome, we will not be reviewing all of this information in detail. However, there is a chance we may uncover health information which would directly impact your care. If the study identifies such information, the study clinician or genetic counsellor involved in your care will contact you to discuss the finding. Should this happen, repeat testing in a clinical laboratory might be recommended to confirm any research results and the benefits and risks as well as possible inconveniences will be discussed with you. Please indicate below if you want to be informed of any incidental findings.

In genetic research, the researchers may learn something about you that they didn't expect. For example, the researchers may identify genes that may predispose you to immune-related disorders such as inflammatory bowel disease This is called a secondary finding. **Secondary findings are information that was discovered unintentionally.**

Some secondary findings may be **medically actionable.** Medically actionable secondary findings mean there is a high chance of a health problem AND treatment and/or screening is available for this health problem.

If we discover medically actionable findings or if any new clinically important information about your health is obtained as a result of your participation in this study, we will let you know. We will only talk to you about those medically actionable findings that we think are likely to have a major effect on health. Seeing a medical specialist could be helpful as there might be specific health recommendations for you and/or family member(s). We will work with you, your family and your doctor(s) during this process. Because many of these variants are passed from parent to child, identification of one of these variants in you could have implications for biological (blood) family members' (such as parent(s) and siblings) health as well. Any medically actionable secondary findings identified through this research study need to be validated in a clinical laboratory. This will be discussed with the doctor involved in your care.

Medically non-actionable findings:
There are also medically non-actionable findings. These findings may indicate there is a high chance for a disease but there is currently no treatment and or screening available (e.g., Alzheimer's or Huntington's Disease). We will not return these findings to you; we do not return information on incidental findings that are not medically actionable. We will not place this information into your medical records at SickKids.

Carrier status information:
Sometimes, secondary findings may reveal information about carrier status. Some people are "carriers" of a genetic disorder; this means they have the gene that causes a disorder but they are not affected by the disorder. Children of carriers may be at an increased risk to have that specific genetic disorder.

Since knowledge of carrier status can be important for future family planning, if we discover a secondary finding about your carrier status of a serious disorder, we can talk with you about that finding. You can choose if you want to receive carrier status information.

We will ask you again about your choices if we have test results to tell you.

Please initial next to your preference about receiving carrier status information:

_____ Initials	Yes, in the event that future genetic testing is performed, I want to be informed if I am a carrier for a major hereditary condition. We will ask you to tell us which groups of disorders you wish to learn about and which you do not.
_____ Initials	No, in the event that future genetic testing is performed, I do not want to be informed if I am a carrier for major hereditary condition.

Please initial next to your preference about receiving carrier status information about your infant:

_____ Initials	Yes, in the event that future genetic testing is performed, I want to be informed if my child is a carrier for a major hereditary condition. We will ask you to tell us which groups of disorders you wish to learn about and which you do not.
_____ Initials	No, in the event that future genetic testing is performed, I do not want to be informed if my child is a carrier for a major hereditary condition.

Empowerment Sub-Study

This is only applicable for participants in the final year of the study. Tick Not Applicable if this does not apply.

Not Applicable ☐

During the final year of the study, 20-30 participants will be invited to participate in interviews at around 4-months after delivery. During this interview, you will speak with a member of the research team. The interview will be about 20-30 minutes in length and will take place either virtually (via Zoom Healthcare, Microsoft Teams and/ or by phone) or in person. You will be asked to provide information about your knowledge and attitude toward the gut health of you and your infant.

You will be audio recorded if the interview takes place over the phone and/ or video recorded if the interview takes place in person. The video/audio recordings will be stored in a secure location and viewed only by members of the research team. The recordings will be kept until they have been transcribed (turned into written records), and then they will be destroyed.

During the discussions, participants will be encouraged to refrain from using names. If names or other identifying information is shared during the discussion, it will not be included in the written records.

Below are options for participation. Please initial next to your preference(s).

Empowerment Interview:	
_____ Initials	Yes, I consent to be approached to participate in the empowerment interview
_____ Initials	No, I do not want to be approached for the empowerment interview

Study Workshops

Towards the end of our study, we will work to develop workshops for participants and healthcare providers that focus on the importance of a healthy gut microbiome during pregnancy and beyond. These workshops will be developed based on participant and doctor feedback.

Below are options for participation. Please initial next to your preference(s).

Study Workshops	
_____ Initials	Yes, I consent to be approached to participate in the study workshops.
_____ Initials	No, I do not want to be approached for the study workshops.