RESEARCH SUBJECT INFORMATION AND CONSENT FORM
Stool Sample Collection

Title of Study:	**The impact of short-term breastfeeding on intestinal microbiome of infants in rural and remote First Nations communities**
Investigators:	**Dr. Garry Shen** University of Manitoba 835-715 McDermot Ave Winnipeg, Manitoba R3E 3P4
Co-Investigators:	Dr. Ehsan Khafipour Dr. Shadi Sepehri Dr. Megan Azad Dr. Brandy Wicklow Dr. Elizabeth Sellers
Partner:	Sandy Bay, Sagkeeng and Garden Hill FN communities
Sponsor:	Children's Hospital Research Institute of Manitoba

THANKS FOR CONSIDERING INVOLVEMENT IN THIS STUDY!
THE RESEARCH WILL HELP OTHERS IN THE FUTURE

The explanation below may help you understand the consent better	**Consent**
The University is doing research (a study). You can be involved if you agree. **The study will be about breastfeeding**	You are being asked to participate in a research study. Please take your time to review this Information and Consent Form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this study and you may discuss it

and preventing diabetes. **We need your "consent" (your "okay") to get information from you. The information will be kept private.** **Please ask any questions you want to.**	with your doctor, friends and family. This consent form may contain words that you do not understand. Please ask the study doctor or study staff to explain any words or information that you do not clearly understand.
WHAT IS THE STUDY ABOUT? **The study is about finding out the difference of bacteria types in the guts of babies who drink formula compare to the babies who are breastfed. Sixty babies will be recruited from First Nations communities.**	**Purpose of Study** The purpose of this study is to examine gut bacteria (intestinal microbiome) in First Nation infants breastfed for short term compared to that in infants not breastfed or breastfed for longer terms, and relationship with the growth and breastfeeding of the infants in rural or remote FN communities. We plan to recruit 60 mothers and their infants from the 3 communities for the study.
What do you need to do? **Please collect stool samples from your baby at 1 month, 3 month, and 6 month of age. The tube and the instructions will be given to you if you agree to join the study. The study staff will collect the tubes from you.**	**Study procedures** The stool sample at each time point (1, 3, 6 months of age of your baby) will be collected from diaper using provided swab and tube, and store the tubes at room temperature follow the instruction. You are expected to submit the samples to Nursing Station or Medical Center, or contact Project Coordinator to collect the samples. *If your baby is delivered through C-section, or you or your baby received antibiotics within last 30 days, please do not collect stool sample and inform the Project Coordinator for advice.
SAFETY **Stool sample collection is safe.**	**Risk and discomforts** There is no risk or discomfort for infant or yourself regarding to stool collection.
The program is free.	**Costs** There is no cost to you for participating in this study.
How the study will help. **You may feel better from being in the study. You may not. You will help scientists understand more.**	**Benefits** You may not benefit from participation in this research; however, the study should contribute to a better understanding of the effect of diet and exercise in pregnant women.

A $30 gift card will be given to you once the tubs are collected from you.	**Payment for participation** A $30 gift card will be given to you once the tubes are collected from you to compensate your time.
Your personal information will be private. **Your name will not be used in the study report. Your identity will not be known to anyone outside the study.**	**Confidentiality** Files that contain your identity will be treated as confidential in accordance with the Personal Health Information Act of Manitoba Personal information such as your name, address, telephone number and/or any other identifying information will not leave the Investigator's office. The Health Research Ethics Board at the University of Manitoba and sponsors of the study may review your research-related records for quality assurance purposes. If the results of the trial are published, your identity will remain confidential.
You can stop being part of the study at any time.	**Voluntary Participation/Withdrawal from the Study** Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. Your decision not to participate or to withdraw from the study will not affect your care at this centre. If the study staff feel that it is in your best interest to withdraw you from the study, they will remove you without your consent. We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.
Please ask questions at any time. **Sign the form only when you are sure that you understand everything.**	**Questions** You are welcome to ask any questions during and after the study. Please contact the people below with your questions. Study Coordinator: Amy Hui Leung, Tel No. (204) 789 3985 Researcher: Dr. Garry Shen, Tel No. (204)789-3816 For questions about your rights as a research participant, you may contact The University of Manitoba, Bannatyne Campus Research Ethics Board Office at (204) 789-3389

Do not sign this consent form unless you have a chance to ask questions and have received satisfactory answers to all of your questions. Please read the consent form carefully before you sign it. Our staff will be happy to help you with any questions.

Statement of Consent

I have read this consent form. I have had the opportunity to discuss this research study with Dr. Garry Shen or his study staff. I have had my questions answered by them in language I understand. The risks and benefits have been explained to me. I believe that I have not been unduly influenced by any study team member to participate in the research study by any statements or implied statements. Any relationship (such as employer, supervisor or family member) I may have with the study team has not affected my decision to participate. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of any of my records that relate to this study by The University of Manitoba Research Ethics Board for quality assurance purposes.

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

_____ *[Optional]* **I agree to be contacted for future follow-up in relation to this study,**
Yes _ No _

Participant signature_____ **Date** _____
(day/month/year)

Participant printed name: _____

Parent/legal guardian's signature_____**Date** _____
(day/month/year)

Parent/legal guardian's printed name: _____

STAFF WILL SIGN BELOW WITH PARTICIPANT PRESENT

I confirm that I have explained the purpose, duration etc of this clinical trial, as well as any potential risks and benefits, to the subject whose name and signature appears above. I confirm that I believe that the subject has understood and has knowingly given their consent to participate by his/her personally dated signature.
Study staff signature: _____ Date/Time: _____

Printed name of above:_____ Study role:_____

RESEARCH SUBJECT INFORMATION AND CONSENT FORM
Breast Milk Collection

Title of Study:	**The impact of short-term breastfeeding on intestinal microbiome of infants in rural and remote First Nations communities: a sub-study for milk microbiome analysis**
Investigators:	**Dr. Garry Shen** University of Manitoba 835-715 McDermot Ave Winnipeg, Manitoba R3E 3P4
Co-Investigators:	Dr. Ehsan Khafipour Dr. Shadi Sepehri Dr. Meghan Azad Dr. Brandy Wicklow Dr. Elizabeth Sellers
Partner:	Sandy Bay, Sagkeeng and Garden Hill FN communities
Sponsor:	Children's Hospital Research Institute of Manitoba

THANKS FOR CONSIDERING INVOLVEMENT IN THIS STUDY!
THE RESEARCH WILL HELP OTHERS IN THE FUTURE

The explanation below may help you understand the consent better	**Consent**
The University is doing research (a study). You can be involved if you agree. **The study will be about breastfeeding and preventing diabetes.** **We need your "consent" (your "okay") to get information from you. The information will be kept private.** **Please ask any questions you want to.**	You are being asked to participate in a research study. Please take your time to review this Information and Consent Form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this study and you may discuss it with your doctor, friends and family. This consent form may contain words that you do not understand. Please ask the study doctor or study staff to explain any words or information that you do not clearly understand.

WHAT IS THE STUDY ABOUT? **The study is about finding out the difference of bacteria types in the guts of babies who drink formula compare to the babies who are breastfed. Thirty mothers and their babies will be recruited from First Nations communities.**	**Purpose of Study** The purpose of this study is to examine bacteria in your breast milk and to determine the relationship with bacteria in mother's milk and infant's stool for preventing diabetes and obesity of your child. We plan to recruit 30 participants from the 3 participating communities for the study.
What do you need to do? **Please collect your breast milk (1-5 ml) at <5 days, 5-60 days and > 60 days. The sterile tube, disinfection wipes and the instructions will be given to you if you agree to join the study.**	**Study procedures** The breast milk samples are expected to be collected in morning at <5 days, 5-60 days and 2 months or more after delivery. You are instructed to wipe one of your breasts with disinfection wipe provided to you, and allow 1-5 ml of milk (up to one table spoon) to drop into a sterile tube with or without mild pressure to the breast. The milk tube is expected to be stored in your refrigerator at 4ºC temporarily. You are expected to submit or call local assistants or Project Coordinator to pick up the sample within 24 hours of the collection. *If your breast feel pain, have known infection in breast or have antibiotics within 30 days, please do not collect breast milk. Please contact Project Coordinator for advice.
SAFETY **The collection of breast milk is safe for you and your baby.**	**Risk and discomforts** There is no risk for the milk collection for mother or baby. You could experience a slight fullness on your breast if you use your hands to press your breast to secrete milk.
The program is free.	**Costs** There is no cost to you for participating in this study.
How the study will help. **You may feel better from being in the study. You may not. You will help scientists understand more.**	**Benefits** You may not benefit from participation in this research; however, the study should contribute to a better understanding of the effect of diet and exercise in pregnant women.

A $50 gift card will be given to you once the tubs are collected from you.	**Payment for participation** A $50 gift card will be given to you for your time compensation and phone calls once the milk collection tubes are submitted.
Your personal information will be private. **Your name will not be used in the study report. Your identity will not be known to anyone outside the study.**	**Confidentiality** Files that contain your identity will be treated as confidential in accordance with the Personal Health Information Act of Manitoba Personal information such as your name, address, telephone number and/or any other identifying information will not leave the Investigator's office. The Health Research Ethics Board at the University of Manitoba and sponsors of the study may review your research-related records for quality assurance purposes. If the results of the trial are published, your identity will remain confidential.
You can stop being part of the study at any time.	**Voluntary Participation/Withdrawal from the Study** Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. Your decision not to participate or to withdraw from the study will not affect your care at this center and your participation in the study for collecting stools from your infant. If the study staff feels that it is in your best interest to withdraw you from the study, they will remove you without your consent. We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.
Please ask questions at any time. **Sign the form only when you are sure that you understand everything.**	**Questions** You are welcome to ask any questions during and after the study. Please contact the people below with your questions. Study Coordinator: Amy Hui Leung, Tel No. (204) 789 3985 Researcher: Dr. Garry Shen, Tel No. (204)789-3816 For questions about your rights as a research participant, you may contact The University of Manitoba, Bannatyne Campus Research Ethics Board Office at (204) 789-3389

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Statement of Consent

I have read this consent form. I have had the opportunity to discuss this research study with Dr. Garry Shen or his study staff. I have had my questions answered by them in language I understand. The risks and benefits have been explained to me. I believe that I have not been unduly influenced by any study team member to participate in the research study by any statements or implied statements. Any relationship (such as employer, supervisor or family member) I may have with the study team has not affected my decision to participate. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of any of my records that relate to this study by The University of Manitoba Research Ethics Board for quality assurance purposes.

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

_____ *[Optional]* **I agree to be contacted for future follow-up in relation to this study,**
Yes _ No _

Participant signature_____ **Date** _____
(day/month/year)

Participant printed name: _____

Parent/legal guardian's signature_____**Date** _____
(day/month/year)

Parent/legal guardian's printed name: _____

STAFF WILL SIGN BELOW WITH PARTICIPANT PRESENT

I confirm that I have explained the purpose, duration etc of this clinical trial, as well as any potential risks and benefits, to the subject whose name and signature appears above. I confirm that I believe that the subject has understood and has knowingly given their consent to participate by his/her personally dated signature.
Study staff signature: _____ Date/Time: _____

Printed name of above:_____ Study role:_____