Title of Study: Innovative Lifestyle Prenatal Program for First Nations Pregnant Women in Remote Communities

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Sponsor: Lawson Foundation

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 pregnancy and preventing obesity and 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 exercise and nutrition in pregnancy. It may help**	**Purpose of Study** The purpose of this study is to examine the effect of an exercise and nutrition education program through social media in helping to prevent obesity and diabetes in pregnancy and promote breastfeeding of your baby. Women who are <26 weeks of pregnancy and their

prevent obesity and diabetes. **We need women who are at the start of their pregnancy.** **You will be asked to do gentle exercise.** **We will talk to you about healthy eating.**	family members may be eligible for this study. The study will continue to your baby reaches 1 year of age. A total of 100 pregnant women will participate in this study. During the study, we will talk about healthy eating for you and your baby. We will ask you to do some gentle exercise on a regular basis during most of your pregnancy. You will be expected to watch the educational videos on social media or on DVD and exercise according to recommendation. Our research assistant will deliver all the educational materials to you and will collect diet and exercise records and weight measurements from you. You will be expected to provide the weight and length of your baby at 1 year of age.
TO BE PART OF THE RESEARCH, your health must be approved / "okayed". **We will ask you health related questions to make sure you are "okay" for the study.**	ELIGIBILITY SCREENING The purpose of the pre-screening is to make sure that it is safe for you to join the study. You will not be allowed to enter the study if you have any of the following: ♦ vaginal bleeding ♦ shortness of breath, or dizziness ♦ chest pain ♦ leg pain or swelling ♦ health problems with pregnancy ♦ heart disease ♦ kidney disease ♦ Severe anemia
	The study will need information from you on • height • weight at different stages of your pregnancy • eating pattern • physical activity level • medical information related to the study which may affect your pregnancy or exercise activity
RISK AND DISCOMFORTS **Gentle exercise is safe for most moms.** **Some people will not be able to join the study. (See list to the right)** **Stop the exercise if you**	**<u>Risk and discomforts</u>** There is little or no risk related to mild or moderate exercise for a healthy mom. You may experience some discomfort during the exercise period. If this happens, you may stop the exercise and let the study staff know. You may feel some discomfort or embarrassment discussing your weight, foods you eat, and activity in your life.

have pain or feel different. **The staff will help you be safe.**	
SAFETY **If you hurt yourself at the program, someone will help you get to a doctor if necessary.** **The study has responsibilities to you. You have legal rights.** **Staff will not be judging you or your life. Staff will be learning from you and you are helping them**.	**Safety** If an injury (such as sprained ankle, blister) occurs to you as a result of taking part in study activities or undergoing study procedures, study staff will help you or to see your doctor if necessary. Safety procedures will be observed at all times by the study staff to protect you and you baby. Every effort will be made to make you feel comfortable physically and emotionally and to enjoy the study program. You are not waiving any of your legal rights by signing this consent form or releasing the investigator or the sponsor from their legal and professional responsibilities.
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. You will receive small gifts for your participation.
The program is free.	**Costs** There is no cost to you for participating in this study.
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.** **You give us permission (your "okay") to see your**	**Confidentiality** Medical records 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 Diabetes Research Group. 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

medical files when you sign the consent form. (Your medical files will give us information we need to do this study.)	confidential. • By signing the attached Informed Consent Form you consent to direct access to your medical records to obtain medical information related to the study which may affect your pregnancy or exercise activity Your personal identifications, including your name, birth date, will not appear on any publication or be exposed to any other individual beside study researchers.
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. Researcher: Dr. Garry Shen Tel No. 204-789-3816 Researcher: Dr. Sora Ludwig Tel No. 204-237-2908 Researcher: Dr. Margaret Morris Tel No. 204-787-3735 For questions about your rights as a research subject, you may contact: The Health Research Ethics Board, University of Manitoba at 789-3883.

Do not agree to 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 agree to it. Our staff will be happy to help you with any questions.

Consent

I understand that as part of the study, I am giving the study staff access to my personal and my child's medical records information that is related to the study. **Yes** ☐ **No** ☐

1. I have read and understood the information of the study and I agree to participate in the study.

2. I understand that I can stop participating in the study at any time, for any reason, and this will not affect my future medical treatment.

 Initials of Participant: _____

3. I agree to cooperate with the study doctors and will tell them if I experience any side effects, symptoms or changes in my health or pregnancy

4. I understand that my name, address, and telephone number will be kept private and all the identifying information will be stripped. I give permission to the health organizations mentioned above to review my medical records.

5. I agree to let the study staff and my family doctor know any discomfort that happen during study program sessions, or let them know any discomfort happens later on, and the growth information of my baby.

6. By signing and dating this document, I am clear that none of my legal rights are being waived. I understand that I will be given a copy of the signed and dated Information and Consent Form.

Signature:_____ Date: _____

Printed name of above:_____

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:_____

Initials of Participant: _____