# CONSENT FORM

## Diabetes Prevention Program Feasibility Study of Breastfeeding

## Sponsor – National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

**Overall Principal Investigator – Lisette T. Jacobson, PhD, MPA, MPA**
**Via Christi Principal Investigator – Michael Wolfe, MD**
**1010 N. Kansas, Wichita, KS 67214; ljacobson@kumc.edu**

You are being asked to join a research study. You are being asked to take part in this study because you are overweight or obese and you are pregnant. The main purpose of this research is to create new knowledge for the benefit of future patients and society in general. Research studies may or may not benefit the people who participate.

Research is voluntary, and you may change your mind at any time. There will be no penalty to you if you decide not to participate, or if you start the study and decide to stop early. Either way, you can still get medical care and services.

This consent form explains what you have to do if you are in the study. It also describes the possible risks and benefits. Please read the form carefully and ask as many questions as you need to, before deciding about participating in this research.

You can ask questions now or anytime during the study. The researchers will tell you if they receive any new information that might cause you to change your mind about participating.

This research study will take place at the University of Kansas School Of Medicine in Wichita with Dr. Lisette Jacobson as the researcher. Approximately 72 people will be enrolled in the study.

## BACKGROUND

In the U.S., diabetes during pregnancy affects 6% to 20% of pregnant women. Pregnant women who are overweight or obese have a higher chance of developing diabetes during and after pregnancy. Diabetes during pregnancy may lead to pregnancy complications, lower breastfeeding rates, and a less than optimal subsequent pregnancy. More importantly, one's chances of developing type 2 diabetes after pregnancy are much higher, and type 2 diabetes increases one's chances to develop heart disease later in life. Weight loss among overweight or obese reproductive-age women will improve pregnancy outcomes and will reduce risk to develop type 2 diabetes later in life. Given how common overweight or obesity is among pregnant women, interventions are needed to address weight loss in this population.

## PURPOSE

By doing this study, researchers hope to learn about the impact of the Diabetes Prevention Program (DPP) coupled with intensive breastfeeding support to help overweight or obese pregnant women lose weight postpartum, improve their blood sugars and blood pressure, and increase duration of breastfeeding their infant.

## PROCEDURES

### Procedures for All Participants

If you are eligible and you decide to participate in this study, your participation will be for up to 12 months. This study is divided into three groups:

Group #1: Diabetes Prevention Program (DPP) plus Breastfeeding
Group #2: Diabetes Prevention Program (DPP) only
Group #3: Usual Care

Upon study entry, you are assigned a number by a computer and this computer will then randomly assign you to one of these three groups. You will then remain in this group for the remainder of the study. You will be asked to provide an email address and telephone number that the research coordinator can use to contact you and call you at the designated times outlined below. No more than 72 participants will be involved in this study.

At about week 18 of your pregnancy, you will have a one-hour in-person (or Skype) orientation session. Upon completion of this consent form and during the orientation/baseline visit, you will be asked to complete surveys to assess your breastfeeding knowledge, use of physical activity, and dietary habits. At any time, you can decline to answer one or more questions on any of these surveys. You will also be asked to have your HbA1c measured, which is a blood test to measure your blood sugars, and to have your blood pressure measured. You will complete the first phase of the program by week 33 of pregnancy and you will have no more than six hours total contact time with research staff during the first phase of the study.

The second phase of the program will start after delivery of your baby. The research coordinator will call you to ask you about your breastfeeding experience, if you supplement with formula, if you've introduced any solid foods, and to provide your baby's height and weight, according to the following timeline:

At days 3 and 10 after birth (at day 3, we will ask about your baby's height and weight at birth)
At weeks 3 and 6 after birth
At months 2, 3, and 6 after birth

These telephone calls will not last longer than 20 minutes. Based on information provided during these calls, the research coordinator may refer you to a professional lactation consultant if needed.

Because a lot of women feel overwhelmed with the birth of their baby, at 6 weeks after birth, you will be asked to complete a survey to assess postnatal depression. If needed, you may be referred to a behavioral health services professional.

Upon delivery and at 6 months after birth, you will again be asked to have your HbA1c measured and your blood pressure measured. You are asked to provide your own weight in pounds to the research coordinator at delivery, weeks 1, 3 and 6 after delivery, and then every week when the research coordinator follows up with you.

At 6 months after birth, you are asked to have another in-person (or Skype) study closure session and you will be asked to complete the same surveys that you completed when you entered the study; these surveys assess your breastfeeding knowledge, use of physical activity, and dietary habits. At any time, you can decline to answer one or more questions on any of these surveys. You will have no more than six hours total contact time with research staff during the second phase of the study.

**Procedures for Group 1 Participants (DPP plus Breastfeeding)**

After your orientation session, the first phase of your participation will involve self-study of the Diabetes Prevention Program (DPP) of one hour per week, participate in one phone call per week from the research coordinator to track progress, attend a 2-hour breastfeeding class in person, and initiate one contact to your local online breastfeeding peer support group.

The second phase of your participation starts at 6 weeks after birth and involves the DPP self-study. The research coordinator will call you every week to collect measurements and to track progress on your self-study until completion of the second portion of the DPP program at week 20 (month 5) after birth. You will also need to post 2 to 4 posts on the online breastfeeding peer support group prior to completing the study. You will have no more than six hours total contact time with research staff.

**Procedures for Group 2 Participants (DPP Only)**

After your orientation session, the first phase of your participation will involve self-study of the Diabetes Prevention Program (DPP) of one hour per week, and participate in one phone call per week from the research coordinator to track progress.

The second phase of your participation starts at 6 weeks after birth and involves the DPP self-study. The research coordinator will call you every week to collect measurements and to track progress on your self-study until completion of the second portion of the DPP program at week 20 (month 5) after birth. You will have no more than six hours total contact time with research staff.

**Procedures for Group 3 Participants (Usual Care)**

After your orientation session, the first phase of your participation will involve following instructions provided by Dr. Wolfe on nutrition and physical activity during pregnancy, and participate in one phone call per week from the research coordinator to track progress.

The second phase of your participation starts at 6 weeks after birth and involves Dr. Wolfe's instructions. The research coordinator will call you every week to collect measurements until completion of the second portion of the instructional program at week 20 (month 5) after birth. You will have no more than six hours total contact time with research staff.

**RISKS**

You are asked to participate in an intervention that is educational. You will learn more about exercise and diet, and will apply these concepts in your daily functioning. During the study, your weight, HbA1c and mean arterial blood pressure, and length of breastfeeding will be measured. During pregnancy, the breastfeeding class is highly visual and interactive. After birth, you will have access to a lactation consultant up to 6 months after birth. There are no known risks of people participating in an educational intervention. All data will be kept anonymous and in a locked file cabinet in a locked office located at the University of Kansas School of Medicine-Wichita (KUSM-W). All data will be entered into a computer; electronic data will be on a secure server at KUSM-W that is backed up on a nightly basis by the IT department at KUSM-W.

A potential risk of participating in the study is a breach of confidentiality and loss of privacy. To further address privacy and to ensure confidentiality, the investigators will ensure the following measures are taken. All data obtained in the study will be kept confidential. The only parties having access to the data in the study will be the principal investigator (Dr. Jacobson), Dr. Jacobson's research team, and the Institutional Review Board of record. Responses to the surveys and the clinical information obtained will be maintained on the KUSM-W REDCap database. Only the necessary members of the research team will have access to the REDCap database.

Participation in this study may be associated with anxiety about weight, breastfeeding, dietary changes, and/or use of physical activity. You might be embarrassed by some of the questions the researchers ask you. You are free to not answer any questions.

You may experience emotional distress as a result of taking the survey to assess postnatal depression. You are free not to answer any questions.

There may be other risks of the study that are not yet known.

**NEW FINDINGS STATEMENT**

You will be told about anything new that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

**BENEFITS**

Findings from this study may be used to conduct a larger trial that can appropriately answer the question about the role of a combined DPP-breastfeeding program to motivate weight loss and reduce risk of developing diabetes after pregnancy among overweight or obese pregnant women. You may or may not directly benefit from this study.

**ALTERNATIVES**

Participation in this study is voluntary. Deciding not to participate will have no effect on the care or services you receive at your local clinic, hospital, or practice.

**COSTS**

Your internet service provider and/or phone company's standard charges will apply during this study. You will not be reimbursed for travel to and from the University of Kansas School of Medicine-Wichita for the in-person session at study entry and at study closure.

**PAYMENT TO SUBJECTS**

You will receive a $50 gift card at consent, after you deliver your baby you will receive a digital scale and pedometer, and upon completion of the study (at 6 months after birth) you may select a gift up to $75 from your baby registry at Walmart. In summary, for participants randomized to any of the three groups: 1) DPP plus breastfeeding, or 2) DPP only, or 3) Usual care, the total possible compensation is $50 plus the following gift items: digital scale, pedometer, and a gift from the baby registry at Walmart for up to $75.

If your participation ends early, you will only receive the items for the program components you completed.

Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if you receive $600 or more in a calendar year.

**IN THE EVENT OF INJURY**

No harm is expected during this study. If you have any problem during the study, you should contact Dr. Jacobson at (316) 293-3484 or the research coordinator.

Via Christi Hospitals Wichita, Inc. does not provide free medical treatment or payment for injuries resulting from participation in biomedical or behavioral research.

**CONFIDENTIALITY AND PRIVACY AUTHORIZATION**

The researchers will protect your information, as required by law. However, absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Your health information is protected by a federal privacy law called HIPAA. By signing this consent form, you are giving permission to use and share your health information. If you decide not to sign the form, you cannot be in the study.

The researchers will only use and share information that is needed for the study. To do the study, they will collect health information from the study activities including lab results that are obtained from the patient's medical records at Dr. Wolfe's office. You may be identified by information such as name, address, phone, date of birth, or other identifiers. Your health information will be used by Dr. Jacobson and members of the research team, the Via Christi Hospitals Wichita, Inc. Institutional Review Board, and other committees and offices that review and monitor research studies. Study records might be reviewed by government officials who oversee research, if a regulatory review takes place.

All study information that is sent outside of the University of Kansas Medical Center will have your name and other identifying characteristics removed, so that your identity will not be known. Because identifiers will be removed, your health information will not be re-disclosed by outside persons or groups and will not lose its federal privacy protection.

Your permission to use and share your health information remains in effect until the study is complete and the results are analyzed. After that time, researchers will remove personal information from study records and your permission to disclose your health information to the researchers will expire.

**QUESTIONS**

Before you sign this form, Dr. Jacobson or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Via Christi Hospitals Wichita, Inc. Institutional Review Board at (316) 268-5114. You may also write the Institutional Review Board, Via Christi Hospitals Wichita, Inc., 929 North St. Francis, Wichita, KS 67214.

**SUBJECT RIGHTS AND WITHDRAWAL FROM THE STUDY**

You may stop being in the study at any time. Your decision to stop will not prevent you from getting treatment or services. Likewise, your participation in this study could also be terminated by the investigator if it is determined you are unable to comply with study requirements. The entire study may be discontinued for any reason without your consent by the investigator conducting the study.

You have the right to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Dr. Jacobson. The mailing address is: Dr. Lisette Jacobson, 1010 N. Kansas, Wichita, KS 67214. If you cancel permission to use your health information, you will be withdrawn from the study. The research team will stop collecting any additional information about you. The research team may use and share information that was gathered before they received your cancellation. If you revoke this authorization, your protected health information may still be disclosed under special circumstances such as an adverse effect or if required by law. There is a potential for information disclosed as a result of this authorization to be subject to redisclosure by the recipient and no longer protected by the HIPAA/Privacy rules.

As the study participant, you will have access to your collected health information during the course of the study.

**CLINICAL TRIALS WEBSITE**

A description of this clinical trial will be available on the http://www.ClinicalTrials.gov website, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of results. You can search this website at any time.

**CONSENT**

Dr. Lisette Jacobson or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.
***You will be given a signed copy of the consent form to keep for your records.***

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Participant Telephone Contact Number

_____
Participant Email Address

_____
Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date