Permission to Take Part in a Human Research Study

University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Title of research study: **Integrated smoking cessation and breastfeeding program (STUDY00003067)**

Version Date: **September 17, 2020**

Investigator: ***Xiaozhong Wen***

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you are eligible for it based on your previous responses to our screening survey (Step 1).

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

Maternal smoke abstinence and sufficient breastfeeding are important for maternal and infant health. The purpose of this research project is to promote smoking abstinence and breastfeeding. We will assess the effect of an integrated intervention of smoking cessation during pregnancy and breastfeeding on maternal and child health.

How long will the research last and what will I need to do?

We expect that you will be in this research study throughout this pregnancy and then until 9 months postpartum. This may take up to 18 months, depending on how long your current pregnancy will last. You will be asked to complete pre-test visit and survey, prenatal smoking and breastfeeding intervention visits, prenatal evaluation survey, end-of-pregnancy visit and survey, post-delivery survey, postpartum smoking and breastfeeding intervention visits, and postpartum follow-up visit and survey. More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

There are minimal physical risks for participating in this study, including possible pain and engorgement during breastfeeding. There are minimal psychological risks for participating in this

study, including embarrassment for surveys, anthropometric measures, and nicotine withdrawal symptoms. There is potential risk of breach of confidentiality.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits include gaining scientific knowledge about promoting maternal smoking abstinence and breastfeeding as well as informing clinical practices and public health policy.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You may choose not to enroll in this study. Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (716) 829-6811 or xiaozhon@buffalo.edu. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 80 (40 pregnant mothers and their to-be-born infants) people will participate in this research study.

What happens if I say yes, I want to be in this research?

Pre-test visit and survey. During the pre-test visit, we will measure your breath carbon monoxide, urine cotinine, height, body weight and blood pressure. You will be asked to complete a survey on smoking temptations, nicotine dependence before quitting, smoking cessation history, self-efficacy to maintain smoking abstinence, partner smoking and smoking environment, health motivation, breastfeeding knowledge, breastfeeding history, partner interaction, relationship with other family members, perceived social support, the Perceived Stress Scale, the Positive and Negative Affect Schedule, breastfeeding knowledge and experience.

Randomization. After pre-test visit and survey, you will be randomized into either the group A or the group (B) to receive different interventions.

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Group A. Participants need to complete 6 weekly prenatal visits and 4 postpartum visits (1, 3, 5, and 6 months) at in our lab or your home (2 weeks postpartum). Two female Certified Lactation Counselors (CLCs) will be trained as interventionist to run these visits. Each visit will last for about 60 minutes. If you are assigned to the Group A, you will receive an integrated intervention of smoking cessation and breastfeeding: education and counseling, monitoring and feedback, and contingent incentives. Each intervention visit will be divided between smoking cessation intervention and breastfeeding promotion intervention. Interventionists will provide additional support via phone and text messaging until 6 months postpartum.

Group B. If you are assigned to the Group B, you will complete the same frequency and duration of visits as participants assigned to the Group A. You will receive best standard care on smoking cessation and breastfeeding, including referral to the New York State Smokers' Quitline and the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). You will also receive detailed instructions on general pregnancy and infant care, guided by two authoritative books: "Your Pregnancy and Childbirth: Month to Month" and "Caring for Your Baby and Young Child: Birth to Age 5", respectively.

Prenatal evaluation visit and survey. After the prenatal intervention, we will measure your breath carbon monoxide, urine cotinine, body weight, and blood pressure. In addition, you will be asked to complete an evaluation survey on updates on your smoking status, smoking temptations, self-efficacy to maintain smoking abstinence, partner smoking and smoking environment, health motivation, breastfeeding knowledge, infant feeding plan, partner interaction, relationship with other family members, perceived social support, the Perceived Stress Scale, the Positive and Negative Affect Schedule, and comfortability to the survey.

End-of-pregnancy visit and survey. At 35 weeks of your pregnancy, we will measure your breath carbon monoxide, urine cotinine, body weight, and blood pressure. In addition, you will be asked to complete the end-of-pregnancy survey on updates on your smoking status, smoking temptations, self-efficacy to maintain smoking abstinence, partner smoking and smoking environment, health motivation, breastfeeding knowledge, infant feeding plan, partner interaction, relationship with other family members, perceived social support, the Perceived Stress Scale, the Positive and Negative Affect Schedule, and comfortability to the survey.

Post-delivery survey. Within 3 days after your delivery, we will ask you to complete a post-delivery survey on your delivery experience and your newborn's birth outcomes. Other information in this survey includes updates on your smoking status, smoking temptations, self-efficacy to maintain smoking abstinence, partner smoking and smoking environment, health motivation, breastfeeding knowledge, partner interaction, relationship with other family members, perceived social support, the Perceived Stress Scale, the Positive and Negative Affect Schedule.

Home visit: We will visit you at your home at 2 weeks postpartum. We will update your smoking and breastfeeding status, test your urine cotinine and breath carbon monoxide, and measure your body weight and blood pressure. You will also need to complete a survey on mother-infant bonding, maternal stress, and maternal negative affect. We will also conduct brief infant care counseling for the Group A, and brief breastfeeding counseling for the Group B.

Postpartum follow-ups. In postpartum, we will ask you to complete once-a-month postpartum surveys and in-person visits at 1, 3, 5, and 6 months during the postpartum intervention period. We will update

your smoking and breastfeeding status, and measure your breath carbon monoxide, urine cotinine, body weight, and blood pressure. You will also need to complete a survey on breastfeeding knowledge, perceived social support, the Perceived Stress Scale, the Positive and Negative Affect Schedule mother-infant bonding, maternal stress, and maternal negative affect.

At 1, 3, and 5 months postpartum, maternal and infant behaviors will be assessed during observations of mother-infant interactions during free play in our clinic. The observation room will be set up with toys on top of a colorful blanket placed on the floor. You will be asked to spend some time with your infant as you normally would at home. These interactions will be videotaped for 10 minutes and independently coded by two coders blinded to group assignment or other information about mothers and infants.

Audio recording and video-recording. All study visits will be audio recorded for quality assurance and training purposes. The mother-infant interaction session will be videotaped. Your permission for audio/video recording will be orally verified before each recording. You have the right to refuse or stop audio-recording at any time during any study visit.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to 1) provide accurate and complete answers to survey questions based on your best understanding, 2) cooperate with our research staff to complete physical examination, lab observation, and lab tests of breath and urine specimens, 3) adhere the intervention program, 4) report the any discomforts that you may feel to the Principle Investigator and your healthcare providers.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

Is there any way being in this study could be bad for me? (Detailed Risks)

There are minimal physical risks for participating in this study. Some mothers may feel pain during breastfeeding especially with poor baby latch. Engorgement may also occur when breasts begin making more milk and the baby cannot empty breasts timely. Both pain and engorgement are normal physiological responses of breastfeeding and usually last for short period of time. We will teach you some skills, such as appropriate latching, breast massage or milk expression, and use of cold compresses between feedings, to help them to reduce pain and engorgement.

There are minimal psychological risks for participating in this study. There may be some embarrassment for your completing socio-demographic variables and anthropometric measures (weight and height). There may be some emotional responses when you report smoking and substance use behaviors. Some smokers may experience nicotine withdrawal symptoms after quit smoking such as nicotine craving, fatigue, anger/frustration/irritability, anxiety, depression, and weight gain. We will provide you a brochure discussing some lifestyle and psychological coping strategies for nicotine withdrawal symptoms. Some women may feel embarrassed to breastfeed in the presence of female research staff. You can use nursing cover during breastfeeding if you want.

There is potential risk of breach of confidentiality during the collection and transfer of data over the internet using SurveyMonkey. But we will minimize the risk by using an arbitrary code number with the questionnaires and data and keeping a master list separate and in a secured location.

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What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Your de-identified data will stored/banked for a reasonably long period as needed. Qualified collaborators may use the de-identified data for additional research upon a signed data use agreement including compliance with HIPPA and other data security policies. If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

Can I be removed from the research without my OK?

The principal investigator of the study can remove you from the research study without your approval. Possible reasons for removal include 1) evidence that you do not pay sufficient attention to survey questions or you provide significant number of invalid or conflicting responses; 2) significant difficulty for you to adhere the program, and 3) evidence that you and/or your baby are not suitable or eligible to continue to be in this research study (e.g., severe pregnancy complications, miscarriage, stillbirth, and severe birth defects).
We will tell you about any new information that may affect your and your baby's health, welfare, or choice to stay in the research.

What else do I need to know?

Who is paying for this research?

This research is funded by a research grant from the National Institutes of Health.

Will I get paid for my participation in this research?

If you agree to take part in this research study, we will pay you up to $440 for your time and effort. Specifically, you will receive $30 at lab screening, $30 at pre-test visit and survey, $60 for the 6 prenatal smoking and breastfeeding intervention visits ($10/visit), up to $35 reward if passing the 7 quizzes on smoking cessation educational materials ($5 reward/quiz), up to $25 reward if passing the 5 quizzes on breastfeeding educational materials ($5 reward/quiz), $15 for prenatal evaluation survey, $25 for end-of-pregnancy visit and survey, $15 for post-delivery survey, $10 for 2-week postpartum visit, $25 for 1-month postpartum visit and survey, $15 for 2-month postpartum survey, $25 for 3-month postpartum visit and survey, $15 for 4-month postpartum survey, $25 for 5-month postpartum visit and survey, $25 for 6-month postpartum visit and survey, and $35 for 9-month postpartum visit and survey. In addition, you will receive another $10 bonus/visit for mother-infant interaction lab observation at 1 month, 3 months, and 5 months postpartum. Therefore, you will receive up to $440 compensation in total, depending on your adherence, group assignment, and performance. The payment will be delivered in cash weekly or as soon as possible after you complete each component of this study.

Study payments are considered taxable income and are reportable to the IRS. If your total study payments are $600 or more in a calendar year, a Form 1099 will be mailed to you.

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HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information and to use or disclose it for the purposes of the research described in this document. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What individually identifiable health information will be collected about you as part of this research study?

__√___ Information from your full medical records: smoking history, medical history, pregnancy complications (e.g., gestational diabetes, hypertensive conditions, anemia), fetal ultrasound measures (e.g., estimated fetal weight, biparietal diameter, amniotic fluid volume), method of delivery, and birth outcomes (e.g. gestational age, weight, length, head and chest circumferences, Apgar score), as well as your infant's growth (e.g., weight, length/height, head and chest circumferences) and health status (e.g., asthma, infection, allergy, ezema, diarrhea, injury, developmental milestones) your infant's medical records. Personal health information will be collected, including your name, mailing address, date of birth, telephone numbers, and medical record numbers.

___√__ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to create or provide this information for research use?

__√___ KALEIDA Health, Buffalo NY
__√___ UBMD Clinical Practice Plan(s) (identify): _UBMD OB/GYN
__√___ Principal Investigator or designee
__√__ Other(s) (identify): Catholic Health System

C. Who is authorized to receive the information from the information providers identified in (B)?

__√_ Principal Investigator or designee

D. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

__√___ Clinical staff not involved in this research study who may become involved in your care if it is potentially relevant to your treatment
__√___ The organization(s) responsible for administering this research: ***Research Foundation of SUNY, UB Foundation Services, Inc..***

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Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

Although safeguards are in place to prevent accidental disclosure of your information beyond the purposes described above, the information disclosed through this authorization is no longer protected by HIPAA. There is the potential for this information to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

E. How long are the information providers listed in (B) authorized to provide your information for this research project?

__√___ a. This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing.

__√___ d. Your protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information. The researchers may continue to rely on this authorization to acquire protected health information about you unless you revoke this authorization in writing.

F. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Xiaozhong Wen, MD, PhD
Division of Behavioral Medicine
Department of Pediatrics
Jacobs School of Medicine and Biomedical Sciences
State University of New York at Buffalo
3435 Main St., G56 Farber Hall
Buffalo, NY 14214-3000
(716) 829-6811

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If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

G. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

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Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

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Signature Block for Parental Permission

Your signature documents your permission for the named child to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Baby (mother's last name)

Signature of parent or individual legally authorized to consent to the child's general medical care

Date

Printed name of parent or individual legally authorized to consent to the child's general medical care

- ❑ Parent
- ❑ Individual legally authorized to consent to the child's general medical care (See note below)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Assent

- ❑ Obtained
- ❑ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

Signature of person obtaining consent

Date

Printed name of person obtaining consent