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: **Infant care and breastfeeding promotion program**

Version Date: **July 19, 2018**

Investigator: Xiaozhong Wen

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.

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"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu
if:
- 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 have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?
Infant care and feeding are important for infant-parent relationship and infant growth and development. The purpose of this research project is to promote positive infant care and breastfeeding. We will assess the intervention effect of infant care and breastfeeding promotion on maternal and child health.

How long will the research last?
We expect that you will be in this research study throughout this pregnancy and then until 9 months postpartum.

How many people will be studied?
We expect about 120 (60 pregnant mothers and 60 family supporters) people will be here in this research study.

What happens if I say yes, I want to be in this research?
Pre-test. During the pre-test visit, we will measure your breath carbon monoxide, urine cotinine, height, and body weight. 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.

Prenatal breastfeeding education. You will receive prenatal breastfeeding education starting in late pregnancy (28+ weeks). Educational approaches will include readings with 5 quizzes ($5 reward if passed), discussion, video, demonstration and practice with a baby simulator. Prenatal breastfeeding education will be delivered during 2 sessions our clinics in UB South Campus in a group with 6 pairs of participants and their family supporters per group. Each educational session is about 2 hours long. At the end of educational sessions, an individualized breastfeeding plan will be developed for you, including breastfeeding on demand, pain management, skin-to-skin contact, breastfeeding tips after cesarean section, lactation support, breastfeeding away from home, breast pump, maternity leave, and back-to-work scheduling. Physical examination of breasts and nipples will be conducted by a certified lactation counselor to address potential issues including infectious conditions, dermatitis, breast masses, breast surgery, and flat or inverted nipples.

Prenatal evaluation survey. After the prenatal breastfeeding education, we will measure your breath carbon monoxide, urine cotinine, and body weight. 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, 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.

At-end-pregnancy survey. At 35 weeks of your pregnancy, we will measure your breath carbon monoxide, urine cotinine, and body weight. 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, 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.

Randomization. If you have relapsed to smoking by delivery, you will be removed from this program. If you are still smoking abstinent by delivery, you will be randomized into either the group A or the group B right after delivery.

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 include 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. With your permission and written consent on sharing health information, we will contact your obstetricians to obtain your clinical results of pregnancy, fetal growth, and delivery from your medical records.

Postpartum infant care education. The group A will receive general infant care education, counseling, and support. The group B will receive infant care specifically focusing breastfeeding education, counseling, and support. To deliver intervention, we will meet you at 2 weeks postpartum in your home and then at 1, 2, 3, 4, 5, and 6 months postpartum in our clinic.

Follow-up. Three months after postpartum infant care education ends, we will invite you and your infant to visit our clinic to complete the 9-month postpartum follow-up.

Outcome assessments. During postpartum visits, we will ask you to complete surveys, lab observations, infant feeding, and blood draws. We will measure your smoking status, breastfeeding status, blood oxytocin and prolactin, mother-infant bonding, mother-infant interaction, stress, and negative affect. The following table shows the schedule for these outcome measures.

Table 1. Schedule for outcome measures

	Pregnancy	**Postpartum (W-week, M-month)**							
Measure	**Enrollment (pre-test)**	**W2**	**M1**	**M2**	**M3**	**M4**	**M5**	**M6 (post-test)**	**M9 (follow-up)**
Outcomes									
Smoking status	X	X	X	X	X	X	X	X	X
Breastfeeding (BF) status	BF intention	X	X	X	X	X	X	X	X
Mediators									
Oxytocin and prolactin			X		X		X		
Mother-infant bonding		X	X	X	X	X	X	X	X
Mother-infant interaction			X		X		X		
Maternal stress	X	X	X	X	X	X	X	X	X
Maternal negative affect	X	X	X	X	X	X	X	X	X

Maternal plasma oxytocin and prolactin. We will measure the baseline and peak levels of these two hormones during a typical feeding session ($40 extra compensation/session) in 1, 3, and 5 months postpartum. We will ask you to bring your infant to our clinic for an observed feeding session in a quiet dedicated room administrated by a female phlebotomist and a female research assistant. A 20 gauge Venflon cannula (tube) will be inserted into your forearm vein to enable 3 small blood draws during the visit without having to insert a needle more than once. A 10-minute habituation period and

another 10-minute baseline rest will be used before a 10.0-mL venous blood sample is obtained to measure baseline oxytocin and prolactin. You will then feed your infant as usual, e.g., breastfeeding, formula feeding, or mixed. We will obtain 10.0-mL blood samples repeatedly at 3 and 30 minutes after the onset of feeding or pumping. Therefore, a total of around 30 ml (about 1 ounce or 2 tablespoons) of your blood will be collected. We will use these blood samples to measure hormone levels related to social bonding (oxytocin) and lactation (prolactin).

Mother-infant interaction. At 1, 3, and 5 months postpartum, maternal and infant behaviors will be assessed during observations ($10 extra compensation/session) 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.

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. 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.

Audio 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, urine, and blood specimen, 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 do not want to be in this research?
Your participation in this research study is voluntary. You may choose not to enroll in this study.

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?
There are minimal physical risks for participating in this study. Venous blood draw may be uncomfortable and/or painful to some participants, and it may carry a very low risk of infection and syncope. 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.

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 smoking pregnant women may experience nicotine withdrawal symptoms after quit smoking such as nicotine craving, fatigue, anger/frustration/irritability, anxiety, depression, and weight gain. There may be some emotional responses (e.g., unpleasant, guilty) for participants' reporting their substance use especially if they know these behaviors may harm their unborn baby. Some women may feel embarrassed to breastfeed in the presence of female research staff. You can use nursing cover during breastfeeding if you want.

In addition, some women may be embarrassed and/or anxious when having their breasts examined by the lactation counselor to address potential issues for successful breastfeeding. The breast examination will be conducted by a female and experienced lactation counselor in a quiet examination room without windows. We will take several other measures to further reduce potential embarrassment and/or anxiety during breast examination: 1) the room temperature will be kept constantly warm throughout the examination; 2) you will undress from waist up privately behind a curtain; 3) a cloth gown with the opening in the front will be provided for you to wear during breast examination; 4) the lactation counselor will warm her hands before examination; 5) the whole breast examination will be conducted without any disturbance, and as efficiently as possible; 6) a female chaperone is available if you prefers.

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.

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 infant care and breastfeeding as well as informing clinical practices and public health policy.

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.

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, 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, severe birth defects, or moving out of Western New York area), and 4) your smoking relapse before delivery.

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?

This program is being funded by a research grant from the National Institutes of Health (NIH). We will pay you for some of your time and resources spent in this program. Specifically, you will receive $30 at lab screening, $30 at pre-test, $15 for the 1st prenatal breastfeeding education visit, $15 for the 2nd prenatal breastfeeding education visit, up to $25 reward if you pass the 5 quizzes on educational materials ($5 reward/quiz), $15 for prenatal evaluation survey, $15 for end-of-pregnancy survey, $30 for post-delivery survey, $15 for 2-week postpartum visit, $15 for 1-month postpartum visit, $15 for 2-month postpartum visit, $15 for 3-month postpartum visit, $15 for 4-month postpartum visit, $15 for 5-month postpartum visit, $15 for 6-month postpartum visit, and $30 for 9-month postpartum. In addition, you will receive another $50 bonus/visit for blood draw and mother-infant interaction lab observation at 1 month, 3 months, and 5 months postpartum. Therefore, you will receive up to $460 compensation in total. The payment will be delivered in cash weekly or as soon as possible after you complete each component of this study.

Permission to Take Part in a Human Research Study

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. Health information is considered "protected health information" when it may directly identify you as an individual. 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. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected 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)

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

Provide a general description of information that will be collected:

B. Who is authorized to provide or collect this information?

__√_ Principal Investigator or designee

C. 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 including Research Foundation of SUNY, UB Foundation Services, Inc.

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.

All reasonable efforts will be used to protect the confidentiality of your protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization 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.

D. How long will this information be kept by the Principal Investigator?

__√___ 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.

E. 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

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.

F. 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.

Permission to Take Part in a Human Research Study

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	

Permission to Take Part in a Human Research Study

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.

Printed name of child

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.

Signature of second parent

Date

Printed name of second parent

If signature of second parent not obtained, indicate why: (select one)

- ❑ The IRB determined that the permission of one parent is sufficient.
- ❑ Second parent is deceased
- ❑ Second parent is unknown
- ❑ Second parent is incompetent
- ❑ Second parent is not reasonably available
- ❑ Only one parent has legal responsibility for the care and custody of the child

Assent

- ❑ Child is birth-6 yrs. old - Assent is not required
- ❑ Child is 7-17 yrs. old – A separate Assent Document is to be signed by the child
- ❑ Assent will be obtained Verbally

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.

Signature of person obtaining consent

Date

Printed name of person obtaining consent

IRB Approval Period