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Informed Consent Form

Official title of the study: Collaborative Perinatal Mental Health and Parenting Support in Primary Care

NCT Number: 02724774

Date of document: 11/21/2016 (date of IRB approval)

Moms & Babies Program
Programa Para Mamás y Bebés
UNIVERSITY of WASHINGTON
FAMILY & CHILD NURSING

UNIVERSITY OF WASHINGTON
CONSENT FORM
MOMS & BABIES PROGRAM

Researchers:

Susan J. Spieker	Principal Investigator	Family & Child Nursing	206-543-8453
Mary Jane Lohr	Project Director	Family & Child Nursing	206-616-3373
Anthippy Petras	Recruitment Coordinator	Family & Child Nursing	206-351-2150

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

The University of Washington is partnering with Wellspring Family Services to offer a home-visiting parenting support program to women receiving health care at several King County community health centers, including Country Doctor, HealthPoint, Neighborcare, SeaMar, Harborview, Seattle Indian Health Board, and Public Health Seattle & King County. The parenting program *Promoting First Relationships®* has been widely used with families. It has recently been adapted for parents with infants. We want to see if the program is helpful for mothers with infants. We want to see if the program is helpful for mothers who speak Spanish or English. And we want to see if the program is successful and could be offered on a wider basis at the clinics. We plan to enroll 240 mother-infant pairs in the study.

STUDY PROCEDURES

The study includes 3 research visits in your home, first when your baby is between 1 and 3 months, and again when your baby is 6 months and 12 months old. You will be involved in the study for about your baby's first year. Half of the families that enroll in the study will receive the *Promoting First Relationships® (PFR)* home visiting program, and half will receive a *Parenting Information & Resources* packet, between the first and second research visits.

Randomization: Because this study is testing the effectiveness of PFR, those who agree to participate will be randomized (like flipping a coin) to receive the study program or not. You cannot pick which group you will be in; it will be determined by chance. After the first research visit, someone from the study will call you to tell you which group you are in.

Promoting First Relationships (PFR): If you are in the group that gets the PFR home-visit program, you will have 10 weekly visits in your home or another place of convenience. You will meet with a parenting support specialist from Wellspring Family Services. The parenting support specialists are trained professionals, and have passed criminal background checks. Each visit would be at a time that is good for you and your baby. Each visit will last about 1 hour. PFR is designed to support parents in understanding their babies' needs, and to enhance a trusting and secure relationship with them. The visits will include time for you and your baby to play together. Five of the visits include about 10 minutes when you and your baby will be videotaped together. The specialist will watch the tapes with you, and give you positive feedback. The sessions will also focus on deeper feelings and needs that lead to behavior problems in children. One of the visits will be videotaped from start to finish so we can make sure the specialist is doing what she is supposed to do.

Parenting Information & Resources: If you are in the group that gets Parenting Information & Resources, you will receive a packet in the mail. It will contain materials about child development, tips for parents, and a list of local resources.

Research Visits: All mothers and babies in the study will have 3 research visits. The first visit would be after you agree to participate. The second will be when your baby is about 6 months old. The final visit will be when your baby is about 12 months old. If we can't schedule your last research visit when your baby is 12 months old, we would continue to try to reach you until your baby is 18 months old. These visits are to collect information for research. The visits include interview questions, and play time for you and your baby. The research visitors have passed criminal background checks.

You will be asked about topics including information about your baby's birth, your feelings and experiences of parenting your baby, your recent mood, current and past stressful events, and background information. Some of the most personal and sensitive questions include whether you were abused or neglected as a child, whether you have recently been in jail or prison, and whether you or a partner have a problem with alcohol or drugs. You may refuse to answer any question.

The mother and baby play portion of the visit will be videotaped (about 15 minutes).

The research visits will each last about 1½ hours.

RISKS, STRESS, OR DISCOMFORT

You may feel that the questions we ask are sensitive, and you may feel uncomfortable answering personal questions about how you are feeling, thinking, and behaving. You or your baby may feel uncomfortable being videotaped. We will do everything in our power to help you and your baby feel as comfortable as possible during the visits. You may take a break at any time. You can refuse to do any study activity. You may end or postpone a visit at any time.

The visits may be inconvenient. We will try to make being in the study as convenient as possible. We will schedule your visits at times that are best for you and your baby. If you are uncomfortable having the visits in your home, we will find another private place to meet.

There is a small risk to your privacy. However, we have measures in place to keep this from happening and we believe these measures will protect your privacy. We will do everything we can to protect your privacy.

Video recordings of you and your baby are part of the study procedures. Portions of the videotapes may be shared with individuals outside of the research team for training or research presentations. At your request, you may review the recordings, and delete portions. These video recordings will be destroyed in 2026, six years after the study ends.

ALTERNATIVES TO TAKING PART IN THIS STUDY

You do not have to be in this study to get parenting services. You can find out about other services you may be eligible for at the clinic where you get health care.

BENEFITS OF THE STUDY

You may enjoy the study research visits, and the chance to share your thoughts and experiences with the research visitor. If you are in the Promoting First Relationships group, you will receive services that may help you and your family. If you are in the Parenting Information & Resources group, you will receive materials that may help you and your family. What we learn from the study may help families in the future. It may help us improve programs offered at community health centers.

SOURCE OF FUNDING

The University of Washington is receiving financial support from the National Institute of Child Health & Human Development to conduct this study.

CONFIDENTIALITY OF RESEARCH INFORMATION

Your privacy is important to us. We will never use your name in reports about this study. We will not place your name on any research data. Instead, we will assign a code number to your information. We will keep the master list that links your name to your code number in a locked cabinet and protected computer files. We will destroy the identifiable information and the link between your name and study number in 2026, six years after the study ends.

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, or your child has suffered from child abuse or neglect, we must report that to the authorities so that you can get help and support.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- authorities, if we learn of child abuse, or the intent to harm yourself or others.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

You will get your choice of $50 in a gift card or cash for each research visit that you complete. You will get a total of $150 if you do all of the research visits.

The study won't cost you anything.

Future studies may develop based on the findings and issues raised by this research. Thus, findings from this study may be applicable to, and incorporated into future research.

RESEARCH-RELATED INJURY

If you think you have a medical problem or illness related to this research, contact Susan Spieker, Principal Investigator, at 206-543-8453 right away. She will refer you for treatment. The UW does not normally provide compensation for harm except through its discretionary program for medical injury. However, the law may allow you to seek other compensation if the harm is the fault of the researchers. You do not waive any right to seek payment by signing this consent form."

Printed name of study staff obtaining consent Signature Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

Printed name of subject Signature of subject Date

Copies to: Researcher
Subject