

RESEARCH CONSENT FORM

Protocol Title: Phone-Based Postpartum Continuing Care: Smoking Cessation Beginning in Pregnancy

Study No.: HP-00054014

Principal Investigator: Katrina Mark, MD, 410-328-4204

Sponsor: National Institutes of Health (NIH)

You have been invited to take part in a study of pregnant and postpartum (the period beginning immediately after the birth of a child) women offered at this clinic, Maryland Women's Center (MWC). The process by which you learn about the study and make your decision is called informed consent. Joining this study is voluntary. When all your questions have been answered, you will decide if you want to be in the study. If you agree to take part, you will sign this consent form. We will give you a signed copy to keep.

PURPOSE OF STUDY

- The main purpose of the study is to improve the existing services to pregnant and postpartum women who smoke or who have smoked tobacco in the recent past. The study will develop and expand treatment and support for pregnant and postpartum women.
- Some pregnant women who smoked prior to pregnancy cut down or quit smoking during pregnancy but start smoking again and in greater amounts once the baby is born. A return to smoking has negative health effects for the baby and mothers. We are concerned about this problem and are interested in developing a continuing care program that extends from pregnancy into the postpartum period.
- As things are hectic soon after a new baby is born, we believe a telephone-based postpartum continuing care program that offers smoking cessation (the act of quitting smoking) counseling is a good way to reach new mothers. This study will test the effectiveness of the phone-based postpartum continuing care (PPCC).
- PPCC takes a hands-on approach to identify women who are having cravings to smoking or have started smoking again. PPCC will help women who are having a hard time and assist them in regaining control over their cravings.
- You will be one of approximately 130 pregnant females age 18 years or older to take part in this study at MWC.
- You can take part in this study if you are less than 27 weeks pregnant and you are planning to keep your baby.

PROCEDURES

- If you agree to participate you will be chosen by chance, like flipping a coin, to one of the following two groups at week 26 of your pregnancy:
 - Standard Continuing Care
 - Experimental Phone-based Postpartum Continuing Care (PPCC)
- Neither you nor the study staff will choose what group you get assigned to. A computer program will assign you to a group. You will have an equal chance of being in either group.
- If by chance you are selected to the PPCC, you will receive in the mail a package with a letter letting you know when you will receive your first call. In the package you will also find a manual called “Healthy Mom, Healthy Baby” to use along with the calls and a pedometer to help you stay fit and healthy during the weeks ahead and beyond. A Counselor will call you in week 36 of your pregnancy and will continue to call you for 6 months. You will receive ten calls from a PPCC Counselor and we encourage you to use the manual to follow along with the calls. All sessions will be digitally recorded for quality control and training purposes. In the calls, the PPCC Counselor will discuss things known to be associated with smoking, such as mood, stress, and partner support. The PPCC counselors will also educate you on how to reduce the risks of nicotine transmission to your infant that are passed by breastfeeding while smoking or smoking in the presence of your child. Each call will take 15-30 minutes. You are encouraged to call in at any time if you are having cravings or would like the support of your PPCC Counselor.
- If by chance you are selected in the Standard Continuing Care group you will receive referrals to a 24/7 smoking quit line.
- As part of the study, regardless of the group to which you are selected, you will have evaluations. The evaluations will ask questions to see how you are doing. We will ask you to answer questions about stressors in your life, your emotional and social support, and your alcohol, tobacco, and drug use.
- The evaluations will occur at six time points:
 - Enrollment (“intake”)
 - 3 months post-intake
 - 6 months post-intake
 - 6 weeks postpartum
 - 3 months postpartum
 - 6 months postpartum
- The evaluations may be scheduled at the same time as your regular appointments or outside of your clinical visits. If you prefer we can come to your home to complete the evaluations.
- As part of the study we will ask for a urine sample to measure the levels of cotinine (a by-product of nicotine) in your body. If the study evaluations are done at the same time as your prenatal and postpartum appointments, we will use the urine you normally give as part of your clinical appointments to test for cotinine levels. If the study evaluations do not coincide with your clinic appointments, we will collect a urine sample from you to test cotinine levels. At the 6 months postpartum time point, we will test the cotinine level of your child. This will be done by placing

cotton rolls or urine collection pads in your child's diaper upon arrival to your visit (at home or at the clinic) and removing the cotton rolls or pads after completing the evaluations to test for cotinine level.

- The evaluations will take no longer than 30 minutes to complete at each time point. The same measures will be completed each time.
- We realize that contact information and living arrangements can change unexpectedly, so to help research staff keep in touch with you over the course of the study and schedule your follow-up evaluations, we would like to gather information about several alternate ways we may be able to contact you. We will document this information on a Locator Form. Research staff from MWC or Battelle Centers Memorial Institute/Public Health Research & Evaluation may attempt to contact you at any of the addresses or phone numbers listed to schedule and/or complete your follow-up evaluations.
- You will be compensated with a Wal-Mart gift card for your time and effort at each study evaluation. There are a total of six evaluations. Bus tokens may also be provided if needed for transportation to the clinic. No incentive will be offered for missed or skipped visits.

POTENTIAL RISKS/DISCOMFORTS:

- You may experience potential risks and discomforts from the study evaluations and the PPCC calls.
- There is a potential risk of breach of confidentiality (privacy). Loss of confidentiality will be minimized by storing data in a secure and locked location and using only research ID numbers instead of your name on both the evaluations and the calls. In order to protect information about your identity and data with your answers, we will keep them in two separate files that are only linked through a research ID. We will only report data on groups of people. Electronic data will be password-protected.
- If there is a question that you are not comfortable answering you do not need to answer it. You can stop at anytime if you do not wish to continue. If you have something very private to say, you have the right to tell the research staff or PPCC Counselor to turn off the recorder.
- Should mental distress be reported to research staff or PPCC Counselor, they will call the National Suicide Prevention Lifeline with you on the line and/or offer appropriate local referrals to resources available.
- In the event that you miscarry, you will be referred to the clinic's on-site psychiatrist and/or social worker for appropriate community referrals for both mental health and smoking cessation. You can choose whether to continue or discontinue participation in the study at that time.
- In the event of preterm birth, you will continue to be in the study and special considerations will be made to conduct follow-up interviews where and when it is most convenient for you.
- There may be risks in this study which are not yet known.

POTENTIAL BENEFITS

- You may or may not benefit by taking part in this study. There is no guarantee that you will receive direct benefit from your participation in this study.
- You may benefit from participating in this study in several ways:
 - your physical health may improve as a result of quitting smoking and staying quit;
 - your unborn child may have fewer physical and behavioral complications and healthier birth outcomes; and
 - you may benefit financially from spending less money on cigarettes.
- All participants may benefit from the knowledge that they are providing information that could improve treatment methods for people who smoke during pregnancy and postpartum.

ALTERNATIVES TO PARTICIPATION

- You may choose not to join this study or stop participating at anytime.
- Whether or not you agree to the study, your ability to receive health care services in this clinic will not be affected.
- If you decide not to take part in this study, you will still receive smoking cessation counseling at this clinic or a referral to other agencies.

COSTS TO PARTICIPANTS

- There will be no cost to you if you take part in this study. Your insurance company will have to pay for any medical care that is not part of this study.

PAYMENT TO PARTICIPANTS

- You will be compensated with a Wal-Mart gift card for your time and effort at each study evaluation. There are a total of six evaluations. Bus tokens may also be provided if needed for transportation to the clinic.
- Here is the payment breakdown for the duration of the study:
 - You will be compensated with a \$15 Wal-Mart gift card at intake visit
 - You will be compensated with a \$20 Wal-Mart gift card at 3 months post-intake
 - You will be compensated with a \$25 Wal-Mart gift card at 6 months post-intake
 - You will be compensated with a \$30 Wal-Mart gift card at 6 weeks post-partum
 - You will be compensated with a \$35 Wal-Mart gift card at 3 months post-partum
 - You will be compensated with a \$40 Wal-Mart gift card at 6 months post-partum
- An additional \$5 Wal-Mart gift card will be given for your child's urine at 6 months postpartum.
- After completing the study you could receive a total of \$170 in the form of Wal-Mart gift cards.
- No incentives will be paid for missed or skipped visits.

- Upon completion of the study, if you are in the PPCC group you may be offered the chance to earn an additional \$25 in cash by participating in a focus group to determine your feelings about specific aspects of the program and its overall helpfulness. ALL PPCC participants will also receive by mail a pedometer.
- There will be no compensation or medical treatment if you encounter research related injury.

CONFIDENTIALITY AND ACCESS TO RECORDS

- Your research records will be confidential (private) and will not be given to anyone without your written permission, to the extent permitted by law. Everyone using study information will work to keep your personal information private.
- The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.
- You will be assigned a special code number that will be used only for this study. This number will be on all study materials. The list linking your name with the special study code will be kept in a double locked room.
- Responses to the questionnaire in the evaluations and or PPCC calls will be kept private.
- Efforts will be made to limit your personal information, including research study and medical 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, U.S. National Institutes of Health (NIH), study staff at Battelle Centers Memorial Institute/Public Health Research & Evaluation, Battelle Centers Memorial Institute/Public Health Research & Evaluation IRB, study data and safety monitors, and ethics committee.
- These individuals will review your records under guidelines of the U.S. Federal Privacy Act. Their job is to make sure that the study is doing what it is supposed to and that research participants are protected.

Certificate of Confidentiality

- To help further protect your privacy, the research staff has obtained a Certificate of Confidentiality from the National Institute of Health (NIH). With this Certificate, the researchers cannot be forced (for example by a court subpoena) to turn over information about you in any U.S. Federal, State, or local civil, criminal, administrative, legislative, or other proceedings.
- The Certificate cannot be used to resist a demand for information from personnel of the US Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of federal Food and Drug Administration (FDA).



- You should understand that a certificate does not prevent you or a member of your family from releasing information about your involvement in this research if you want to. Note, however, that if an insurer, employer, or other person learns about your participation and you say it is all right for them to have this research information, then the investigator may not use the Certificate of Confidentiality to withhold this information from them. This means you must actively protect your own privacy. You have to be careful about whom you permit to look at your research information.
- The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project if we find out about child/elder abuse, harm to self/others, etc., as we will report it to the appropriate authorities.

RIGHT TO WITHDRAW

- Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at anytime. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator Dr. Katrina Mark at 410-328-4204.
- There are no adverse consequences (physical, social, economic, legal, or psychological) if you decide to withdraw from the research. If you decide not to take part in this study, you will still receive smoking cessation counseling at this clinic or a referral to other agencies. If you decide later to drop out of the study, you may do so by sending your decision in writing to Dr. Katrina Mark at 11 South Paca Street, Suite 400, Baltimore, MD 21201.
- You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.

CAN I BE REMOVED FROM THE RESEARCH?

The investigator Dr. Katrina Mark, the study staff at Battelle Centers Memorial Institute/Public Health Research & Evaluation, or sponsor can decide to withdraw you from the study at any time. You could be removed from the study for reasons related solely to you (for example, not following study-related directions). Also, the Institutional Review Boards, the University, Battelle Centers Memorial Institute/Public Health Research & Evaluation, or the funder may stop the study.



UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as greater than minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is greater than minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland School of Medicine
Human Research Protections Office
BioPark I
800 W. Baltimore Street, Suite 100
Baltimore, MD 21201
410-706-5037



Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

As part of the study we will test cotinine levels in your body from your urine sample. If you agree or refuse to the release of your urine sample collected at each prenatal and postpartum visit for cotinine testing please indicate below.

_____ I agree to the release of my urine sample for the purpose of cotinine testing.

_____ I refuse to the release of my urine sample for the purpose of cotinine testing.

As part of the study we will test cotinine levels in your child's urine at 6 months old. Cotton rolls or urine collection pads will be placed in your child's diaper. At the end of the visit, the cotton rolls or urine collection pads will be removed from the diaper. If the cotton rolls or urine collection pads are dry or your child has not urinated, the research staff will return again within the same week. There is no risk to your child of placing the cotton rolls or pads in his/her diaper. If you agree or refuse to the release of your child's urine sample for cotinine testing please indicate below.

_____ I agree to the collection of my child's urine for the purpose of cotinine testing.

_____ I refuse to the collection of my child's urine for the purpose of cotinine testing.

If the research staff at MWC is unable to reach you for any of the six evaluations the research staff from Battelle Centers Memorial Institute/Public Health Research & Evaluation will attempt to reach you and complete the evaluations over the phone or via email. If you agree or refuse to be contacted to complete the evaluations via phone or email please initial below.

_____ I agree to be contacted via phone or email to complete the evaluations.

_____ I refuse to be contacted via phone or email to complete the evaluations.

If any of the six evaluations are completed via phone or email, your study compensation will be mailed to your home address via certified mail. If you agree or refuse to have your compensation mailed to your home please initial below.

_____ I agree to have my compensation mailed by certified mail to my home address.

_____ I refuse to have my compensation mailed by certified mail to my home address.

If you agree to participate in this study, please sign your name below.

Participant's Signature

Date

Investigator or Designee Obtaining Consent Signature

Date

