

Appendix F6: Consent Form

CONSENT TO PARTICIPATE IN THE WIC PEER COUNSELING STUDY

Please read this form carefully. Your local WIC office is taking part in a national study of WIC's breastfeeding peer counseling services. Abt Associates Inc., a research company in Massachusetts, and its partner, Abt SRBI, are doing this research study on behalf of the Food and Nutrition Service (FNS) at the U.S. Department of Agriculture.

What is the study about? The purpose of this research is to find out how WIC agencies can best use peer counseling to encourage women to breastfeed their infants. Peer counselors are women who breastfed their own babies and get special training from WIC to help other women learn about breastfeeding. Peer counselors talk with women about any breastfeeding concerns or questions. Your local WIC office already has a standard peer counseling program. As part of this study, your local WIC office will provide women in the study either their standard peer counseling services or their standard services plus two extra peer counseling sessions (called the "Standard Plus" program):

1. When you are in the hospital after you deliver your baby, your peer counselor will call you or meet with you in-person.
2. During the first 10 days after you deliver your baby, your peer counselor will meet with you in-person, at your home, in the WIC office, or at another location that is convenient for you.

The study asks what effect the extra sessions have on the choices that women make about breastfeeding. Until the study is finished, we will not know if the standard peer counseling program or the Standard Plus program is better for helping women breastfeed.

How does the study work? If you agree to take part in the study, researchers will randomly assign you to receive either your local WIC office's standard peer counseling program, or the "Standard Plus" program. Random assignment is like flipping a coin: you have an equal chance of being in the standard peer counseling program or the "Standard Plus" peer counseling program. Half of the women in the study will be in the standard program and half will be in the Standard Plus program.

Who can take part in the study? Women who are expecting their first child and who agree to peer counseling are invited to take part in the study. Between 4 and 8 local WIC offices across the country are participating in the study. The research team is asking 1,800 women to participate in the study.

What will researchers ask women in the study to do? If you decide to take part in the study, your local WIC office will give your name and contact information to the study team. The study team will assign you, at random, to receive either the Standard peer counseling program or Standard Plus peer counseling program. A study team member will call you while you are pregnant to ask you some questions about what you think about breastfeeding and how you plan to feed your baby. Answering these will take 15 to 20 minutes. After you complete this first survey you will get \$20. You can refuse to answer any question that you don't want to answer. The researchers will ask you to call a toll-free number when you have your baby and tell them your baby's date of birth. If you call this number within two weeks after you have your baby, you will get a \$5 gift card to a store like Target or Wal-Mart. A few months after you have your baby, a study team member will call you to answer a second set of questions about how you are feeding your baby and about your experiences with the WIC peer counseling program. After you complete this second survey, you will get another \$20. This survey will take 15 to 20 minutes. You can refuse to answer any question that you don't want to answer. If you take part in the study, your local WIC agency will share information with the study team about your peer counseling sessions, such as the date and duration of your sessions and the breastfeeding topics your peer counselor discussed with you.

What happens to the information the study collects? Members of the study team respect your privacy. The members of the study team will keep your personal information private to the extent allowed by law. Your name and your baby's name and date of birth will not appear in any study report. No one at your local WIC office or any other WIC office will know what answers you give during the telephone surveys. The study team will not give FNS your name, your baby's name, birthdate or anything that identifies you or your baby. Personal information about your peer counseling sessions will be kept private to the extent allowed by law. Information about your individual peer counseling sessions will not appear in any study report. Only summary information about peer counseling sessions with all women participating in the study will be reported, not information about you personally.

Who can answer questions about the study? Someone at your local WIC office can answer questions about the study. Also, the Study Director at Abt Associates or the Project Officer at the Food and Nutrition Service can answer questions about this study. Their contact information is below. If you have questions or complaints about your rights as a research participant, you should contact Teresa Doksum, Institutional Review Board Administrator at Abt Associates, at 877-520-6835 (toll-free).

Carter Epstein, Abt Associates Inc., (800) xxx-xxxx or carter_epstein@abtassoc.com
Joseph Robare, Food and Nutrition Service, USDA, (xxx) xxx-xxxx (toll-call).

What are the risks of participation? There are no risks of physical harm to you or your baby. Some of the questions we ask you may make you uncomfortable. For example, we may ask about your beliefs about breastfeeding, your marital status, and your race or ethnicity. You may refuse to answer any questions you do not want to answer. There is very little risk that information about you could be revealed to someone outside the research team.

What are the benefits of participation? This study may not benefit you directly. We do not know if the Standard Plus program benefits women and their babies more than the standard peer counseling program. The two programs may be equally beneficial. The results of this study may benefit other mothers in the WIC program, however.

What happens if I do not want to participate? Participation is voluntary. If you do not wish to participate, you will still receive all of the WIC benefits for which you are eligible. If you do not wish to participate, you can still enroll in your WIC office's peer counseling program, but you will not be able to receive the Standard Plus peer counseling services.

What happens if I want to participate now but I change my mind later? If you ever decide that you want to stop participating in the study, you may. You will still receive all of the WIC benefits for which you are eligible. To stop participating in the study, tell your peer counselor, someone at your local WIC office, or a member of the study team. If you decide to stop participating, the research team can still use information that you gave while you were taking part in the study.

I have read this form. I agree to participate in the study. I understand what my participation in the study involves. I understand I am free to stop participating in the study at any time without any change in the WIC benefits for which I am eligible. A copy of this form has been given to me.

Name of study participant (PRINTED)

Signature of study participant

Date

Name of Person Administering this Form (PRINTED)

Signature of Person Administering this Form

Date