DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
Baby Steps II: SMS scheduled gradual reduction text messages to help pregnant smokers quit

You are being asked to take part in this research study because you are pregnant and you smoke cigarettes. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As the study staff member discusses this consent form with you, please ask her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

A grant from the National Cancer Institute (NCI) will sponsor this study. Portions of Drs. Kathryn Pollak, Laura Fish, Geeta Swamy, and Bercedis Peterson's salaries will be paid by this grant.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to evaluate a program to help women attempt to quit smoking during pregnancy. If our program is effective, we can help women quit smoking during their pregnancy.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Up to 700 women will be enrolled into this study from various sites, including Duke University affiliated clinics, various North Carolina County Health Departments, and Womack Army Medical Center in Fayetteville, NC.

WHAT IS INVOLVED IN THE STUDY?
If this study is right for you and you agree to be in this study, you will be asked to meet in a private and convenient location to read and sign this consent form and then complete a survey about yourself and your smoking. We will then ask to meet with you twice more - once during the late third trimester of your pregnancy and once approximately 3 months after your baby is born – to complete two more surveys. The first meeting will take about 45 minutes. The other two meetings will each take about 30 minutes.

After completing the first survey, you will be randomly assigned (like the flip of a coin) to either a texting program that sends messages to a cell phone that support you as you attempt to quit smoking (Group A) or a texting program that includes the same messages plus smoking reduction text messages (Group B). These smoking reduction messages help change patterns of smoking. Specifically, the program will send an "alert text" at times the program has you scheduled to smoke. These alert texts will be reduced over three to five weeks. You will be offered a cell phone with unlimited texting in the study, or you may choose to use your personal cell phone.

If you are assigned to Group A, you will begin receiving support text messages during the first week after you complete the first survey. You will receive text messages each day for the first 7 weeks. After those 7 weeks, you will receive messages on approximately three days per week, until the 35th week of your pregnancy. You do not have to respond to these messages.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
Baby Steps II: SMS scheduled gradual reduction text messages to help pregnant smokers quit

If you are assigned to Group B, you will receive these support text messages. In addition, you will receive texts that ask you to smoke at random times, not times you might want to smoke. The point is to break the link between smoking and your behaviors. The program starts first by seeing how much you smoke and when you smoke. So in the first week, you will be asked to text each time you smoke. Then starting in the 2nd week, you will receive the "alert texts" that let you know when to smoke. This program will gradually reduce the number of cigarettes you smoke each week over three to five weeks until you get to zero. After you receive an alert text, we ask that you text back within 30 minutes whether you smoked or not. We also ask that you text any time you smoke when you do not get an alert text.

While we request that you respond via text message to some of the messages we send you, we ask that you do not text responses to our messages while driving.

We may audio record some of your answers to the surveys. We will seek verbal permission from you to audio record your answers at the time of the surveys. The audio recordings will be stored electronically on a password protected, encrypted computer that will be kept in a locked office at Duke University. The recordings will not be shared with anyone outside of the research team. Once the study is complete, the audio recordings will be destroyed. You have the right to refuse to be audio-recorded, and it will not impact your ability to participate in this study.

If you decide to use a cell phone provided by the study, the study staff may provide this phone number to your prenatal care provider so that they can text you for care-related issues if needed.

Please initial one of the following statements:

_____ I agree to have my study cell phone number provided to my prenatal care provider
_____ I do not agree to have my study cell phone number provided to my prenatal care provider

You will also be asked to give two saliva samples at the time of the first and second surveys. You may also be asked to give two saliva samples at the time of the third survey. One saliva sample will be used to look at your nicotine (main chemical in cigarettes) levels to see how much smoke you have been exposed to. The second sample will serve as back-up in the event that we are unable to get a proper reading from the first saliva sample. The saliva sample involves spitting directly into a small plastic tube.

Additionally, you may be asked to have up to 20ccs (approximately 4 teaspoons) of your blood drawn from a vein in your arm at the time of your first and second surveys. This blood will be tested for how your genes and DNA improve as a result of your reducing or quitting smoking. Your genes are made up of DNA, which is short for deoxyribonucleic acid. A gene, or DNA, contains information that determines in part the traits, such as eye color, height, or disease risk, that are passed on from parent to child.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
Baby Steps II: SMS scheduled gradual reduction text messages to help pregnant smokers quit

The genetic portion of this study related to the blood we collect from you is for research purposes only. It is not the purpose of this study to look for or provide you with any medical information or diagnoses relating to your present condition or any other disease or illness. The blood we collect is not being used in diagnostic tests for any disease or illness. Your participation in this research project is not a substitute for your regular medical care or check-ups.

By agreeing to participate in this research, you authorize DUHS and members of its staff to use your blood samples for the purposes described in this consent form. DUHS will maintain these samples indefinitely or until they are exhausted. You will not have access to the blood sample once it is obtained. These samples are unavailable for clinical (diagnostic) purposes. Therefore, if you need any future diagnostic testing, a new sample will be obtained from you. Blood samples collected as part of this study may be valuable for scientific, research, or teaching purposes or for the development of a new medical product. DUHS and/or the developers will assert all rights of ownership in the samples and all rights arising from use of the samples. There is no plan to compensate you for any use of the samples.

Trained staff members will draw the blood and will seek verbal permission to do so at the times of the surveys. You have the right to refuse to have your blood drawn, and it will not impact your ability to participate in this study.

Please initial one of the following statements:

_____ I agree to have my blood drawn as part of this study
_____ I do not agree to have my blood drawn as part of this study

As part of the study, you may also be asked to have your picture taken at the time of the 2nd survey. These pictures will be printed and provided to you at the time of your 3rd survey and will serve as a pregnancy keepsake. We will seek verbal permission from you take your picture at the time of the survey. If you do not wish to have your picture taken, you can refuse this offer, and it will not impact your ability to participate in this study.

Lastly, study staff will access your and your baby's medical records at the time of delivery to get information about the baby's birth, such as your baby's gender, gestational age, birth weight, and any medical complications associated with your baby's birth. You may be asked to sign a separate form to permit your information to be sent from the hospital where you delivered your baby to us.

HOW LONG WILL I BE IN THIS STUDY?
If you agree to participate, you will be in the study until approximately 3 months after your baby is born. Depending on when you enroll in the study, this is a total of approximately four to nine months.

Your participation is voluntary. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
Baby Steps II: SMS scheduled gradual reduction text messages to help pregnant smokers quit

WHAT ARE THE RISKS OF THE STUDY?
Quitting smoking may cause nicotine withdrawal that may lead to headaches, irritability, weight gain, difficulty concentrating, poor sleep, increased appetite, anxious or depressed mood, and craving for cigarettes. The counseling provided via text message is designed to help you deal with many of these issues. Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although very unlikely. The genetic information obtained as a result of your blood draw will not be included in your medical record. The Genetic Information Nondiscrimination Act (GINA) is a Federal law that will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research;
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment;
- GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

There is also the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the surveys. You may stop your participation in this study at any time.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to participate in this study, there may be a direct medical benefit to you and/or your baby because you might cut down or quit smoking. What we learn from you and the other women in the study will help us develop programs that will be useful for other women and their families in the future.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Study records, audio recordings, photographs, and saliva and blood samples that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law or for your care, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be assigned a unique code number. In addition, all saliva and blood samples and photographs will be marked with your unique code number for storage at DUHS in accordance with Duke's Institutional Review Board guidelines and policies.

The information that links you to the unique code identification number will be kept in a password-protected and access-restricted database that is stored on a secure server at Duke and is accessible only

to the individuals who work on this study. Any paper files will be kept in locked file cabinets located in the offices of the research staff. All data collected throughout the study on you, except for the select data described below, will be stored on a secure server at Duke that is accessible only to the individuals who work on this study.

- The texting gateway system used for delivering the text messages to and from your cell phone will store the phone number you use for sending and receiving messages, along with the content of the text messages you will receive or send.

As part of the study, Dr. Pollak and her study team will report the results of your participation to the NIH. Your records may be reviewed to meet federal or state regulations. Reviewers may include representatives of the NIH and the Duke University Health System Institutional Review Board. If anyone reviews your records for this purpose, they may need to review your entire medical record. This information may be further disclosed by the sponsor of this study, National Institute of Health. If disclosed by the sponsor, the information is no longer covered by the federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

The study results will be retained in your research record for at least six years after the study is completed. At that time the research information will be destroyed or information identifying you will be removed from such study results at DUHS.

WHAT ARE THE COSTS?
There will be no additional costs to you as a result of being in this study.

WHAT ABOUT COMPENSATION?
You will receive $20 for your completion of the first survey, $25 for the second survey, and $30 for the third survey. You will also receive an extra $20 for completing all three surveys, which will be given to you at the third survey. If you are assigned to Option 2 and respond to 80% of the study's smoking reduction text messages, you will also be entered into a raffle to win $25.

You may be provided with a cell phone with unlimited texting to use until the time of your second survey (around the end of your pregnancy). Alternatively, you may choose to use your personal cell phone that has unlimited texting instead of one we provide to you. If you choose to use your personal cell phone, it is because you anticipate having it from the time of enrollment into the study until 3 months after your baby is born.

If you agree to be in this study and if you want to receive payment, we will ask you to provide your social security number or ITIN number. You do not have to give us this information to participate in the study, but you will not receive compensation if you choose not to provide it.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
Baby Steps II: SMS scheduled gradual reduction text messages to help pregnant smokers quit

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke University Health Systems. Nonparticipation or withdrawal from this study will not affect your job status if you are a Duke employee and will not affect your grades if you are a Duke student.

If you do decide to withdraw, we ask that you contact Dr. Kathryn Pollak in writing and let her know that you are withdrawing from the study. The mailing address is 2424 Erwin Road, Suite 602, Durham, NC 27705.

If you decide to withdraw your permission to use your blood samples in this research project, please contact the study doctor, Dr. Kathryn Pollak, in writing at the mailing address above and let her know you are withdrawing your permission for your blood samples to be stored and used for this or future research. At that time, we will ask you to indicate in writing if you want your unused samples destroyed or if your samples (with all identifying information removed that would link the sample to you) could be used in research. Data collected using your sample before your withdrawal will continue to be used as part of the study. You can still choose to continue your participation in the study, even if you withdraw your permission to use your blood samples.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have complaints, concerns or suggestions about the research, contact Dr. Kathryn Pollak at (919) 681-4757 or the study coordinator, Alicia Bilheimer at (919) 681-4558 during regular business hours and Dr. Pollak at (919) 602-2485 after hours and on weekends and holidays. For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
Baby Steps II: SMS scheduled gradual reduction text messages to help pregnant smokers quit

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time