Combined Consent and HIPAA Authorization to Participate in a Research Study

Tobacco use in Pregnancy Intervention for Cessation

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study to help us understand if and how our program, Tobacco use in Pregnancy Intervention for Cessation (ToPIC), can help pregnant women stop smoking. ToPIC is a new and innovative program which combines intensive smoking cessation education with tobacco evaluation questions your provider may already ask during your office visit. You are being invited to take part in this research study because you are a pregnant woman, age 18-44 and currently or have recently used tobacco. If you volunteer to take part in this study, you will be one of about 120 Kentucky women to do so.

WHO IS DOING THE STUDY?

The researcher in charge of this study is Kristin Ashford, PhD, WHNP-BC, a women's health nurse practitioner and researcher from the University Of Kentucky College Of Nursing. There will be other people on the research team assisting at different times during the study at your clinic.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of our study is to determine the differences in mom and baby outcomes among participants who receive the individualized ToPIC tobacco cessation counseling compared to those who receive the standard tobacco use counseling from their clinic provider. We will also examine smoking behaviors among all participants to help us decide if the program can be done on a larger scale. In addition, we will determine if the ToPIC participants and clinic staff find the program beneficial and acceptable. By implementing our ToPIC program, we hope to successfully help women reduce or stop smoking.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

If you are under 18 years of age or older than 44 years of age, are not pregnant, are not eligible for Medicaid, and/or do not read and write in English, you should not take part in this study.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

This program will include two groups of patients in University of Kentucky prenatal clinics. One group will receive usual care services provided for pregnant tobacco users, which includes a 5-step intervention approach for tobacco cessation as recommended by the American Congress of Obstetrics and Gynecologists (ACOG) which takes approximately 5-15 minutes, and is offered at each prenatal and postpartum appointment, regardless of whether or not you participate in this study. Additionally, participants in this group will complete a 15-20 minute survey, provide a urine sample for cotinine analysis (determines amount of nicotine in your urine), and complete an Expired Air Carbon Monoxide (EACO) analysis two times during pregnancy and two times after delivery. A second group of participants will receive the same 5-step tobacco cessation services (approximately 5-15 minutes) as offered by the clinic, plus individual ToPIC tobacco cessation counseling with a Certified Tobacco Treatment Specialist at least once each month, which may be completed at routine scheduled prenatal visits or via telephone, and is individualized to the participant ranging 15-30 minutes. The group of participants in ToPIC will also complete a 15-20 minute survey, provide a urine sample, and complete an EACO analysis two times during pregnancy and two times after delivery. In total, the participants will spend between 20-65 minutes each session of the program, based on their respective group. Participants will be randomly assigned to the usual care group or the ToPIC group.

WHAT WILL YOU BE ASKED TO DO?

At four times during the study, twice during pregnancy and twice after you deliver, you will be asked to complete an online survey (administered via a password protected iPad), provide a urine sample to determine the amount of nicotine in your urine, and complete an EACO analysis. The surveys, urine cotinine measures, and EACO analysis will occur at your initial study visit before 20 weeks gestation, 28-34 weeks gestation, 2-8 weeks after you deliver, and 12-18 weeks after you delivery. Each of these four surveys will take approximately 20 minutes. After completion of the survey, urine analysis, and EACO measure at each of the two visits during your pregnancy, you will receive a $10 WalMart gift card. After completion of the survey, urine analysis, and EACO measure at each of the two visits after your delivery, you will receive a $20 WalMart gift card. The total potential amount of WalMart gift cards for completing all four surveys, urine analysis, and EACO measures is $60. In addition to the surveys, you will receive the 5-step tobacco cessation services monthly throughout your pregnancy provided by your healthcare provider, which is usually 5-15 minutes in length and is provided regardless of your participation in this study. Additionally, if you are among the ToPIC participant group, you will also receive individualized tobacco cessation counseling with a Certified Tobacco Treatment Specialist (CTTS) monthly at scheduled prenatal visits or via telephone for 15-20 minutes.

Table 1. Summary of Study Procedures

Time points	ToPIC participants	TTAU participants	Outcome	Gift Card
Patient Participants:				
Baseline <20 weeks gestation	• Urine cotinine • EACO • ACOG tobacco use screen • TUQ	• Urine cotinine • EACO • ACOG tobacco use screen	Eligibility screen for tobacco cessation counseling/treatment	$10
Monthly through end of pregnancy at regularly scheduled prenatal visits	• CTTS tobacco treatment education support, including • Individualized treatment plan (baseline) • 5As • Motivational Interviewing • Navigation to resources	• 5As, as per usual		
28-34 weeks gestation	• Urine cotinine • EACO • TUQ	• Urine cotinine • EACO • TUQ	Tobacco cessation or reduction	$10
Postpartum 2-8 weeks after delivery	• Urine cotinine • EACO • TUQ	• Urine cotinine • EACO • TUQ	Tobacco cessation or reduction	$20
Postpartum 12-18 weeks after delivery	• Urine cotinine • EACO • TUQ	• Urine cotinine • EACO • TUQ	Tobacco cessation or reduction	$20

Finally, at the conclusion of our study, you may be asked to participate in a focus group to discuss your opinion about the program. The focus group will be voice recorded, professionally transcribed by a UK employee, and analyzed using computer software. Voice recordings will be safely deleted in accordance with the University of Kentucky procedures for record destruction, once they have been checked against the transcripts for accuracy.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The potential risks of participating in this program include: (1) you may feel uncomfortable discussing tobacco-related issues or answering questions related to the topics in the survey; (2) loss of confidentiality of data; (3) risks inherent in everyday life (for example, experiencing an injury while traveling to the clinic). There is always the possibility that you may experience a previously unknown risk or side effect while participating in this study.

Participation in this program is voluntary and you may stop at any time without any adverse consequences. We will also make every effort to protect against loss of confidentiality of data. All research team members who take part in data collection, data analysis or data storage will be certified in human subject protections through the Collaborative Institutional Training Initiative program (CITI). While you are a participant in the study, all data will be stored in a locked cabinet in your clinic, or on a password protected computer or tablet with encryption. Once you have completed the study, all of your data will be stored in a locked cabinet in a locked research office in the UK College of Nursing Office of Research, or on a password protected computer or tablet with encryption. Prior to starting the program and any focus groups, the importance of confidentiality will be discussed with all the group participants.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no guarantee that you will get any benefit from taking part in this study. Participation in this study may help some women stop smoking, which would reduce the risk of many health problems. Your willingness to take part, however, may help us design a smoking cessation program that may be used in a larger population.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the program, it should be because you want to volunteer. You can stop at any time during the program and still keep the benefits and rights you had before volunteering. If you decide not to take part in this program, your decision will have no effect on the quality of medical care you receive.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to participate in the program, you can use the standard tobacco treatment options, including the Kentucky QuitLine (QuitNow 1-800-784-8669; www.QuitNowKentucky.org) or smoking cessation group sessions if offered through local resources such as a health department (Cooper Clayton or Freedom from Smoking) or community organizations. You can also contact your healthcare provider for more information related to smoking cessation.

WHAT WILL IT COST YOU TO PARTICIPATE?

Whenever possible, your study appointment will be coordinated with your prenatal or postpartum appointments in the clinic. You are responsible for travel and parking costs associated with visiting the clinic. There is no cost to participate in this study other than the time spent participating in program-related activities.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep confidential all research records that identify you, to the extent allowed by the law. Your information will be combined with information from other people taking part in the program. When we write about the program to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this program; however, we will keep your name and other identifying information private. We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. We will use a code number, and not your name on your survey. Surveys and electronic data will be collected on a password protected laptop or tablet with encryption. We will keep all participant records in a locked cabinet in the respective clinic during the study, and in a locked cabinet in our research office in the UK College of Nursing after you complete the study.

You should know, however, that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court or to tell authorities if you report information about a child being abused or if you pose a danger to yourself or someone else.

Officials of your healthcare clinic and University of Kentucky may look at or copy pertinent portions of records that identify you.

CAN YOUR TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the program, you have the right to decide at any time that you no longer want to continue. Your choice to withdraw early from the study, will have no impact on the medical care you receive in your prenatal clinic. However, early withdrawal from the study will terminate your opportunity to earn the gift cards for completing the required sessions. Additionally, the PIs may terminate your participation from the research without your consent if you refuse to participate in the study measures as described in the "What Will You Be Asked To Do" section above.

ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You can take part in this study if you are currently involved in another research study. It is important to inform the person enrolling you in this study if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you believe you have become sick because of something that is due to the study, you should immediately contact your healthcare provider. In the case of emergencies, call 911 or go directly to the Emergency Room. Next, you should call Kristin Ashford, PhD, 859-257-9333.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this program. Also, the University of Kentucky does not have funds to pay for any wages you may lose if you are harmed by this study.

The medical costs related to your care and treatment because of research-related harm will be your responsibility. You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

Walmart Gift Card: At four times during the study (twice during pregnancy and twice after delivery), you will be asked to complete an online survey (administered via a password protected iPad), provide urine for cotinine analysis, and complete an EACO analysis. After completion of the survey, urine analysis, and EACO measure at each of the two visits during your pregnancy, you will receive a $10 WalMart gift card. After completion of the survey, urine analysis, and EACO measure at each of the two visits after your delivery, you will receive a $20 WalMart gift card. The total potential amount of gift cards for completing all four surveys time points is $60.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns or complaints about the study, you can contact the investigators, Dr. Kristin Ashford at (859) 257-9333, the program manager, Andrea McCubbin at (859) 323-6650, or a Perinatal Research Nurse at 859-218-2890. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky, between the business hours of 8am and 5pm EST, Monday-Friday, at (859) 257-9428 or toll free at (866) 400-9428. We will give you a signed copy of this consent form to take with you.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

If the researcher learns of new information in regards to this study, and it might change your willingness to stay in the study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WHAT ELSE DO YOU NEED TO KNOW?

This study is supported by a research grant from the University of Kentucky Center for Health Services Research, Value of Innovation to Implementation Program. The information you provide in your survey and/or your smoking data may lead to new research ideas, diagnosis or treatment. There are no plans to provide financial compensation to you should this occur.

A description of this clinical trial will be available on ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. This form describes how researchers may use your information. Please read it carefully.

Your health information and that of your baby will be used and/or released (disclosed) for the following research study: *Tobacco use in Pregnancy Intervention for Cessation.*

You allow (or authorize) Kristin Ashford, PhD, WHNP-BC, and the research staff at the University of Kentucky to create, access, use and release your health information and the health information of your baby for the purposes listed below.

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information and that of your baby.

Your health information and smoking data that may be accessed, used, and/or released includes Medical Record prenatal data, ACOG record, birth record information, demographics, survey data, delivery and infant outcomes (date of delivery, birthweight, gestational age, complications), and NicAlert analysis (urine cotinine).

Your health information and smoking data will be used to:

- Develop a successful smoking cessation program,
- Determine if the ToPIC program is a feasible program,
- Determine the acceptability of the ToPIC program, and
- Ensure that the research meets legal, institutional or accreditation requirements.

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity
- Law enforcement agencies when required by law
- University of Kentucky Hospital or UK representatives
- UK College of Nursing and Public Health
- Providers and healthcare staff at your prenatal clinic
- Primary physician will be contacted if research in the course of the project learns of a medical condition that needs immediate attention

The researchers agree to only share your health information with the people listed in this document. Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You will not be allowed to participate in the research study if you do not sign this form. If you decide not to sign the form, it will not affect your:

- Current or future healthcare at the University of Kentucky
- Current or future payments to the University of Kentucky
- Ability to enroll in any health plans (if applicable)
- Eligibility for benefits (if applicable)

After signing the form, you can change your mind and NOT let the researcher(s) release or use your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to: Kristin Ashford, APRN, PhD, University of Kentucky College of Nursing, 750 Rose Street CON447, Lexington, KY 40536-0232 to inform her of your decision.
- Researchers may use and release your health information already collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).
- You may not be allowed to participate in the study.

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights as related to this study, you should contact the University of Kentucky's Privacy Officer at: (859) 323-1184.

Study Related Communication

I give permission for a member of the research staff to use text or verbal telephone messages to communicate with me while I am participating in this study. **I understand the messages will include study related information, but not include Protected Health Information (PHI). Text messaging should NOT be used in emergency situations and will NOT be checked outside of normal research study hours from 8am-4pm, M-F.**

I understand that communication via text may not be secure and there is some level of risk that information transmitted via text message could be read or otherwise accessed by a third party. There is no assurance of confidentiality when communicating via text messaging, and the use of text messages carries a risk of inadvertent disclosure through the mistyping of text/contact names or numbers.

I understand that additional charges and fees may be applied by my mobile device service carrier. I understand that I am responsible for any fees that may occur as a result of this communication.

(Please mark one and initial.)

☐ Yes ☐ No _____ (Initials)

You are the subject, and have read this information, and you will receive a copy of this form after it is signed.

_____ _____
Signature of research subject Date

_____
Printed name of research subject

_____ _____
Signature of authorized study personnel obtaining informed consent/HIPAA Date

_____
Printed name of authorized study personnel obtaining consent/HIPAA

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Signature of Principal Investigator/Co-Investigator