Study Title: Smoking Cessation Intervention for Women Living with HIV
NCT NO: NCT02898597

January 31, 2017

Consent Form for **Smoking Cessation Intervention for Women Living with HIV**

Principal Investigator: Sun S Kim, PhD, APRN

Description of the Project
You are being asked to take part in a research study. This research study is looking at women living with HIV and studying strategies to help these women who want to quit smoking. Dr. Kim works at the University of Massachusetts Boston (UMB). Please kindly read this form and feel free to ask questions. If you have more questions later, you can discuss these with Dr. Kim and her telephone number is 201-388-2656.

Procedure of the Study
This study involves written questions, telephone interviews, counseling and a special test of the liquid in your mouth (spit). You will have counseling and nicotine patches at no cost to you. How you get the counseling will be decided by chance, like flipping a coin. Half of the women in the study will get the counseling by telephone voice calls and the remaining half will get it by telephone video calls. You will have the counseling once a week for 8 weeks and each session will last no longer than 30 minutes. The patches will be provided for 8 weeks and you need to apply one patch at a time as directed. You will be asked to start the patch on the first day of quitting.

Before the counseling, you will be asked to sign and return this consent form. You will be also asked to complete written research questions about your age, schooling, attitudes toward living with HIV, drugs, alcohol use, smoking, and your confidence in resisting smoking temptation and bad moods. Your answers to these questions will help us identify your needs to stop smoking and provide the right advice.

Counseling will be the same for everybody. The only difference is how the counseling is provided (telephone video or telephone voice call). The advice is given to help you quit. After the day you quit you will be counseled on how to manage withdrawal symptoms of smoking.

You will be followed over 6 months from the target quit day and asked about some of the questions that you have answered before. This is to see if there are any changes in your answers after the counseling and whether the changes will continue. We will follow you at 1-, 3-, and 6-months from the first day of quitting. You will be asked to participate in all follow-up assessments and perform a spit test at 3-, and 6-month follow-ups even if you are not able to quit smoking. You will be assisted by a research staff who will watch how you conduct the test via telephone video call. So, you will be asked to do a video call during the test, even if you have the counseling by telephone voice calls. The follow-up will take about 5-10 minutes at 1-month follow-up and about 30-40 minutes when you perform the spit test at 3- and 6-month follow-ups.

What Will Be Done
Your participation in this study will take the following schedule.

Timeline of the Study

Week 1st – 3nd	**Week 2nd – 4th**	**Week 4th - 11th Month 1st – 2nd**	**Week 20th Month 5th**	**Week 32th Month 8th**
Screening Interview, Informed consent form & Baseline Data collection	Random assignment upon receiving signed consent form	8 counseling sessions, 8 weeks of nicotine patches & post-quit 1-month follow-up	Post-quit 3-month follow-up & 1st Saliva cotinine test	Post-quit 6-month follow-up & 2nd Saliva cotinine test

Risks

You may experience uncomfortable feelings when you quit smoking. If you have a thought of hurting yourself because you are too sad after you quit or because you start to smoke again, please call the toll-free suicidal hotline or 911. You may experience some side effects of patches such as rashes, upset stomach, headache, dizziness, fast heart beats and strange dreams. All these things occur at about 10-15% of people and most of them are mild. They will disappear once you stop using the patch. If you have severe headache, dizziness, vomiting or blisters on the area where you have applied the patch, you should immediately take off the patch and call Dr. Kim at (201) 388-2656.

Another possible risk is bad feelings when doing the telephone interview. You may want to speak with Dr. Kim at (201) 388-2656 to discuss these feelings.

You may also feel embarrassed and uncomfortable if you report that you have not been smoking but the saliva test shows that you have been smoking. We will explain its possible causes to you if it happens. If you find out you are going to have a baby during the study, patches may hurt your baby. So, you must agree to use an effective birth control during the study. If you become pregnant, you will be advised not to use patches. However, you will be allowed to stay in the study and continue to get advice and follow-up calls.

Another risk of being in this study is that your personal information could be lost or become known by others. This is very unlikely to happen, and we will do everything we can to make sure that your information is protected. However, if we learn that you plan to hurt yourself or others, we will break confidentiality to help you. If we learn of any child or elder abuse, we are required to tell the authorities.

Benefits

Being in this study may help you quit smoking successfully. In addition, the knowledge and findings gained from this study may help us develop a smoking cessation intervention that is effective for women with HIV infection.

There will be no clinic visits. You will interact with three staff members, including Dr. Kim and Ms. Darwish. The study will be conducted from July 2016 to May 2018. You will receive a Visa gift card of $30 by mail when you return your signed consent form and completed research questionnaire. You will receive a Visa gift card of $25 at 1-month follow-up and $50 at 3- and 6-month follow-ups when you perform the spit test. In order for us to mail the patches, spit test kits and gift cards to you, you will be asked to provide us with your home address.

Confidentiality
We will not tell anyone about your being in this study. The information will not be published or presented in a way that would allow anyone to identify you. Information gathered for this research study will be stored in a locked file cabinet and only we will have access to the data. We will also try to limit access to your personal information to people who have a need to review this information. The UMB committee that reviews, approves, and monitors studies may want to see your name; however, they can't share the information with others. Personal identifying information will be destroyed upon the completion of the study.

Voluntary Participation
Your decision whether or not to take part in this research study is **voluntary**. You have the right to choose not to participate. You may stop at any time without any problem. If you wish to stop, you should phone Dr. Kim at 201-388-2656. If you stop, you will not lose anything. You can ask us to destroy any information that identifies you if you leave the study.

You have the right to ask questions about this study before you sign this form and at any time during the study. You can reach Dr. Kim at 201-388-2656. If you have any questions or concerns about your rights as a research participant, please contact a representative of the Institutional Review Board (IRB) at the University of Massachusetts Boston, which oversees research involving human participants. They may be reached at the following address: IRB, Quinn Administration Building 2-080, University of Massachusetts Boston, 100 Morrissey Boulevard, Boston, MA 02125-3393. You can also contact by telephone or e-mail at (617) 287-5370 or at human.subjects@umb.edu.

This study involves audiotaping your counseling sessions. Your name or any other information linking you to the study will be protected by storing the information in a password-protected electronic file and a file in a locked cabinet. The tapes will be erased once they are checked for accuracy. Neither your name nor any other identifying information (such as your voice) will be used in presentations or in written products resulting from the study. After the counseling, you will be given a chance to have the tape erased if you wish to withdraw your consent to taping or participation in this study.

By checking the box in front of the item below and signing this form, you are consenting to participate in that procedure.

☐ Having your counseling sessions audiotaped.

☐ Having the tape transcribed.

☐ Use of the written transcript in presentations and written products.

This consent for audio recording is effective until January 31, 2018. On or before this date, the tapes will be destroyed.

I HAVE READ THE CONSENT FORM. MY QUESTIONS HAVE BEEN ANSWERED. MY SIGNATURE ON THIS FORM INDICATES THAT I CONSENT TO PARTICIPATE IN THIS STUDY.

_____ _____

Signature of Participant **Date**

_____

Typed/Printed Name of Participant

_____ _____

Signature of Researcher Date

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Typed/Printed Name of Researcher