Patient Participant in RCT Informed Consent Form

Date: March 10, 2022

NCT: NCT05162911

NYU Langone Health

Patient Participant in RCT Informed Consent Form

Title of Study:	Implementing tobacco use treatment in HIV clinics in Viet Nam S19-01783
Principal Investigator:	Dr. Donna Shelley MD, MPH NYU School of Medicine NYU College of Public Health Nam Nguyen, MD DrPH Institute of Social and Medical Studies 810 CT1A ĐN1, Ham Nghi Street, My Dinh 2 Ward, South Tu Liem District, Ha Noi, Viet Nam Email: ntnam@isms.org.vn Tel: +84-4-35558288
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1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study. The study is being led by researchers from the Institute of Social and Medical Studies, an organization located in Hanoi, and New York University, located in the US. We will describe the study and answer any questions you may have. If you decide to take part in this study, we will ask you to sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

We are conducting a study to learn more about how we can help smokers quit. We will be comparing three different ways to help smokers quit to see which one works best. Patients who smoke and agree to participate in the study will be assigned randomly (like a flip of a coin) to one of these three different strategies. Everyone who participates will receive brief advise to quit from your health care provider. Group one will also be referred to the Vietnam national Quitline which offers free telephone counseling to help smokers quit. Group two will receive 6-sessions of smoking cessation counseling from the clinic nurse and text messages to provide additional help to quit. Group 3 will also receive 6-sessions of smoking cessation counseling from a trained clinic nurse and text messages. In addition, group 3 received nicotine gum for 6 weeks.

3. How long will I be in the study? How many other people will be in the study?

Your participation in the study regardless of which group you will be assigned will last for one year. We plan to enroll 672 patients across 14 clinics.

4. What will I be asked to do in the study?

If you choose to participate and sign this consent, you receive support to quit that will varying depending on which group you are place into.

For Group 1: We will share your telephone number with the National Quitline so that one of their trained counselors can call you to provide more support to help you quit. Quitlines offer multiple sessions of telephone counseling that can help you stop smoking. When they call, you have the choice of whether you want to speak to them. You can also reschedule to receive counseling when it is convenient, or you can decide that you do not want to speak with them.

For both Group 2 and 3 you will be asked attend 6 sessions of counseling with a trained nurse at your OPC. The first will be in person and the other 5 can be in person or by telephone depending on what you prefer. A trained nurse in this clinic will provide the counseling. Today you will be asked to schedule an appointment in the next 7 days to attend the first counseling session.
We will also send you text messages 2 times per day for the first 8 weeks and then daily to provide additional support in between counseling sessions.

For Group 3 will also receive 6 weeks of nicotine gum. You will be instructed how to use the gum. At each counseling session the nurse will ask how many pieces of gum you have used since the last visit.

All participants will be asked to complete a survey now, 3 months from now when you complete the program and at 6 and 12 months after you complete the program. We may also ask you to participate in a 20–30-minute interview so that we can hear about your experiences with the program.

If you report that you have quit smoking at the 6-month survey you will be asked to return to the clinic to complete a test to confirm that you are no longer smoking. This is called a carbon monoxide test. You will be asked to blow through a small tube into a small machine that can measure the amount of carbon monoxide in your lungs which is increased when someone has recently smoked a cigarette.

Communicating with the Research Team
Researchers may be need to communicate with you about information relevant to the research study. The research team will usually contact you for these purposes by phone, but if you have given the Researchers your email address and mobile/cell phone number and permission to send a text message, the research team may contact you that way. The research team will not send messages that include identifiable health information. When the research team uses texting over mobile/cell phones there is no way to encrypt the message. This means that information you send or receive by text message is unencrypted and could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier. Therefore, text messages carry security and privacy risks.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore are unsecure and may result in a breach of your confidentiality.
- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and NAME OF SITE will not cover the cost related to any increased charges, data usage against plan limits or changes to data fees from the research texts
- Text messages will only be read during regular business hours. However, if you have a scheduled visit outside of business hours, you may receive a text in relation to this visit outside of regular business hours.

- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.
- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says “Stop Research Text.”
- Your agreement applies to this research study only. Agreeing to other texts from NAME OF SITE, for example appointment reminders, is a separate process. Opting out of other texts from NAME OF SITE is a separate process as well.

Please make sure to keep the research team updated if your mobile/cell phone number changes during the study.

_____ Yes, I agree to receive texts from this research group. _____ Initial here

____No, I do not agree to receive texts from this research group. ____Initial here

5. What are the possible risks or discomforts?

If you are randomized to group 3 you will be given information about how to use the gum and what to do if you have any side effects. Nicotine gum may cause mild side effects like nausea, palpitations, dizziness, heartburn, or headache, or trouble sleeping, jaw or tooth discomfort. Most people using this medication do not have serious side effects. Side effects are more likely if you continue to smoke while using this product. Quitting smoking can cause nicotine withdrawal symptoms including dizziness, anxiety and depression. If any of these withdrawal symptoms or side effects persist or worsen, tell your doctor.

6. What are the possible benefits of the study?

Participating in this study may increase your chances of quitting.

7. What other choices do I have if I do not participate? Can I leave before the study ends?

Your participation is voluntary. If you decide not to participate, we will give you a brochure that offers information that may help you quit and has the Smokers’ Quitline number so that you can call if interested. Even after agreeing to participate, you can withdraw at any time. Your withdrawal from the research will not affect your treatment at the health center.

8. Will I be paid for being in this study?

After completing each survey, we give you $3 to thank you for your participation.

9. Will I have to pay for anything?

There will be no cost to you for being in this research study.

10. How will you protect my confidentiality? If you decide to consent to be in this research study and sign this form you are giving us permission for your personal identifiable information, including your name, address and phone number, to be used for this study. You have the right not to sign this form allowing us to use and share your personal information for research. This is your choice. If you do not sign this form, you cannot take part in this research study. This is because we need to use the personal information of everyone who takes part in this research study.

We are recording some of the counseling sessions so one of your sessions may be recorded. Once transcribed the recordings will be deleted. The transcriptions will not include any information that can be linked to you.

New York University and the Institute of Social and Medical Studies (ISMS) are committed to protecting the privacy and confidentiality of your information. No identifying information will be included on the surveys or interviews you complete and the results will be stored in a password-protected computer at ISMS. Every effort will be made to keep your personal information confidential. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/ or publications.

11. Who may use and share information in connection with this study?

By signing this form, you authorize the following persons and organizations to receive your protected health information for purposes related to this research study:

- The research team at New York University and the Institute of Social Medical Studies includingthe Principal Investigators, Drs Nguyen and Shelley, study coordinators, and personnel responsible for the support or oversight of the study.
- The study sponsor: National Institutes of Health.
- The Vietnam smokers Quitline if you are part of group 1.

12. Can I change my mind and withdraw permission to use or share my information?

Yes, you may withdraw or take back your permission to share your responses at any time. To withdraw your permission, you will be able to let the research staff at ISMS know by calling Trang Nguyen at 84-4-35558288.

12. The Institutional Review Board (IRB) and how it protects you.

The IRB reviews all human research studies – including this study. The IRB follows rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible.

13. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at 84-24-3555-8288 ext 109

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date