Informed Consent Form

Official Title:

Early-phase Studies of a Tailored Evidence-Based Smoking Cessation mHealth App for Persons Living with HIV

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DUKE UNIVERSITY HEALTH SYSTEM

Name: _____

DOB: _____

Consent to Participate in a Research Study
Pilot Study of a Tailored Evidence-Based Smoking Cessation mHealth App for People with HIV (PWH)

CONCISE SUMMARY

The purpose of this research study is to test the feasibility, acceptability, and preliminary efficacy of a novel smoking cessation smartphone application (app) for people with HIV (PWH). This study consists of 5 study visits that will take about 12 weeks (or about 3 months) to complete.

If you are eligible to participate, you will be assigned to one of two smoking cessation apps and asked to use it for the next 3 months. You will receive an 8-week course of nicotine replacement therapy (NRT) patches. During the study visits, you will also complete questionnaires and be interviewed about your experience using the app.

The biggest risks of participating in this trial are withdrawal symptoms if you stop smoking, side effects from NRT, and possible loss of privacy/confidentiality.

If you are interested in learning more about this study, please continue reading below.

You are being asked to take part in this research study because you are an every day smoker with HIV/AIDS over the age of 18. 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 your study doctor or study staff discusses this consent form with you, please ask him/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.

Please tell the study doctor or study staff if you are taking part in another research study.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Roger Vilardaga's and his research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. Paolo Mannelli will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed. He will be available to the research team to consult on any medical concerns and respond to any emergency arising from the study procedures.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to test the: (1) feasibility (is it possible for PWH to use this app to quit smoking?), (2) usability (do PWH find this app easy to use?), and (3) preliminary efficacy (does this app work in helping PWH quit smoking?) of a novel smoking cessation smartphone app for people with HIV (PWH) called "Learn to Quit-HIV," or "LTQ-H" for short. This app is investigational, meaning it is still being tested in research studies and its effectiveness is not yet known.

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Name: _____

DOB: _____

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The Learn to Quit app was developed by Dr. Roger Vilardaga, Principal Investigator. Currently, this app is not available to the public, and is only available to you as a participant in this study. It is owned by Duke University and the University of Washington, as it was developed and tested in both institutions. If the technology is commercially successful in the future, the developers and these two universities may benefit financially. We will be comparing the LTQ-H app with another app created by the National Cancer Institute (NCI) for the general public called "QuitGuide", which was not developed by the research team.

Findings from this research will help the study team develop a finalized version of this app which will then be tested for efficacy in a larger sample of smokers living with HIV.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 60 people will take part in this study at Duke University Medical Center.

WHAT IS INVOLVED IN THE STUDY?
This study will be completely remote. All five visits will be done over Zoom video calling. We will provide you with a link to the Zoom call prior to each of your study visits. We ask that during your scheduled visit you find a quiet, private place to talk with us, as we will discuss some sensitive topics.

Screening Visit
After reading through this consent form and going over a brief PowerPoint Presentation, you will be asked to sign and date this consent form if you agree to participate. You will then complete the following procedures to make sure that you are eligible:

- Giving the study team your personal and contact information
  - Demographics questionnaire
  - Filling out a Release of Information (ROI) form that will allow us to communicate with your healthcare provider throughout your study participation
- Completing questionnaires
  - Medical history questionnaire
  - Psychiatric assessment questionnaires
  - Questionnaires related to smoking status
  - Questions about your experience living with HIV

Following the screening visit, the study team will review your eligibility to participate in the study. Once we determine this, we will contact you to let you know of your eligibility status. If you are eligible, we will schedule your next visit.

Baseline Visit
If you pass these initial screening measures, you will be contacted by study staff to schedule a baseline session. During this visit, we will:

- Complete more questionnaires about your mental and physical health
- Ask about your smoking status since your last visit

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- Ask you to complete a survey about your internet and smartphone use

You will then be randomly assigned (like the flip of a coin) to receive either LTQ-H or a comparator app (QuitGuide). You have a 1 in 2 (50%) chance of receiving either app. All participants will receive an 8-week course of nicotine replacement therapy (NRT) patches regardless of app assignment. Study staff will instruct you on how to download your assigned app onto your smartphone, then give you a brief overview of the app including how to use the app's basic functions. During this visit, we will also ask you to pick a quit date prior to your next study visit (within 4 weeks of receiving the app).

After the baseline visit is completed, we will mail your 8-week supply of NRT patches. We ask that you contact us when you get your NRT in the mail, and then we will go over the instructions on how to use the NRT patches properly. We will ask you to keep your used NRT patches for counting at each follow-up visit. At the follow-up visits, we will count both the used and unused patches to see how many you have used since your last visit.

Follow-Up Visits

After completing the baseline visit, we will schedule you for 3 monthly Follow-Up sessions where you will complete more assessments. The visits will occur 4 weeks (FU1), 8 weeks (FU2), and 12 weeks (FU3) after the baseline visit. You will complete the following measures at the follow-up visits:

- Questionnaires about your mental and physical health
- Questionnaires about your smoking/quitting status
    - Using a calendar to recall how many cigarettes you smoked in the past month and how often you used NRT
- Questionnaires about your assigned app
- Being interviewed by research staff about your experience using your assigned app
    - This portion of the visit will be audio recorded

If you have quit smoking by the last follow-up session (FU3), you will be mailed a small device that measures the amount of CO in your lungs by giving a breath sample. If you are told to do a breath test, we will provide detailed instructions on how to do so. We will also ask you to complete the breath test over a Zoom call with research staff to ensure that you are using the device correctly, and to record the result of your CO breath test. Once you successfully complete this CO test, you will get to keep the device.

We will also be collecting background analytics about your app engagement throughout your time in the study. This includes how often you use the app, and what app features you use. The study app is the only app for which we will collect this data; we will not be tracking your smartphone use or any of the other apps that you use. Since the LTQ-H app is not yet publicly available, we will have you delete the app from your phone at the end of the study. If you are assigned to QuitGuide, you can keep the app on your phone if you choose but request for you to delete your subject ID number off the app since we will no longer be collecting data from you.

DUKE UNIVERSITY HEALTH SYSTEM

Name: _____

DOB: _____

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Pilot Study of a Tailored Evidence-Based Smoking Cessation mHealth App for People with HIV (PWH)

HOW LONG WILL I BE IN THIS STUDY?
Study participation is 12 weeks (or about 3 months) long.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your treatment provider first. If you choose to withdraw, you will be asked to complete a termination visit, return any unused NRT and delete the app and/or your subject ID from the phone.

WHAT ARE THE RISKS OF THE STUDY?
Physical Side Effects: As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

Nicotine Replacement Therapy (NRT): NRT patches may cause some, all, or none of the side-effects listed below:

- Itchy or irritated skin where the patch is placed
- Insomnia, vivid dreams
- Dizziness, lightheadedness
- Rapid heart rate, increased blood pressure
- Nausea

Nicotine Withdrawal Symptoms: Quitting smoking cigarettes may also cause mild symptoms called withdrawal symptoms. Though these feelings can be uncomfortable, they are of minimal risk. Common withdrawal symptoms include:

- Cravings for cigarettes
- Feeling irritable, on edge, or grouchy
- Having trouble concentrating
- Feeling down or sad
- Restlessness
- Feeling hungrier than usual

We will be monitoring these symptoms throughout your participation in the study. If we think that participating in the study is putting your health at risk, we may have to withdraw you from the study.

Reproductive Risks:
For women: Smoking is associated with an increased risk of bad outcomes in pregnancy, including miscarriage, preterm birth, and stillbirth. Although nicotine replacement therapy is sometimes used to help pregnant smokers quit, the changes your body undergoes during pregnancy could affect your response to the other interventions in the study. Women who are pregnant or planning a pregnancy during the next 6 months are not allowed to participate in the study.

Subject Initials_____

DUKE UNIVERSITY HEALTH SYSTEM

Name: _____

DOB: _____

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You and your partner should use effective methods of contraception to avoid pregnancy during the study. These methods include (a) partner vasectomy, (b) bilateral tubal ligation, (c) intrauterine devices, (d) barrier methods (condoms, diaphragms, cervical caps) plus spermicide, or (e) hormonal methods (birth control pills, implants, injections, patches, vaginal rings). Depending on your age and other medications you may be taking, some of these methods may not be appropriate. Your study doctor will review your birth control method with you to make sure it is appropriate and meets the requirements of this study. Because no birth control method is 100% effective, you should notify your study doctor immediately if you think there is any chance you could be pregnant.

Loss of Privacy/Confidentiality: The research team will be taking very careful steps to ensure your information remains strictly confidential. All study files are kept in locked filing cabinets in locked offices. All digital data is stored on secured Duke School of Medicine servers. However, there is always the possibility there may be an unauthorized disclosure of your personal information.

Uncomfortable or Embarrassing Tasks: You may be asked to answer questions and do tasks that may cause discomfort or embarrassment, including:

- Answering questions about your medical history, psychiatric symptoms, and HIV status
- Answering questions about your familiarity with technology
- Using a smartphone and app, which could be embarrassing if you are not familiar with this technology

You may skip a question you do not wish to answer; however, not answering certain questions could affect your eligibility to participate in the study. You may stop the interview at any time, and you may do so without penalty.

Video/Audio Recordings: We will be audio and video recording your user experience interviews at FU1 and FU3. All of these recordings will be stored securely on DUHS servers. If you are concerned about being video recorded, you may turn your video off during the recording portion of each visit.

Audio recordings are only reviewed by the research team and a contracted transcription service. All audio recordings will only be labeled by your participant ID number, and will not contain any information that can identify you unless you explicitly share that information in the audio recording. At your request, you may:

- Review the audio recording of your interview
- Stop the recording at any time
- Ask that portions of the recording (or the entire thing) be erased

Mobile Phone Risks: Jailbreaking (rooting) of smart devices poses a serious security risk and is not allowed as stated in the Secure System Usage Memo (http://security.duke.edu/policies-procedures).

Information collected by mobile applications or 'apps' is subject to their terms of use, which you should read carefully. Many apps make claims that they are very secure, compliant with federal privacy

Subject Initials_____

regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and Duke cannot guarantee that these mobile apps are free of risk. Some apps may be able to perform hidden functions or may have security flaws that allow unauthorized access to information. We are unable to fully tell you what information these mobile apps are able to access or change on your device (phone/tablet) or what information from your device may be stored outside of Duke. You are encouraged to limit personal identifiers you enter into mobile applications (particularly your name, date of birth, address, place of employment, and other details that could allow someone to identify you) only to those that you wish to voluntarily share with others. These apps may send/receive information with other mobile apps, including social networking apps or websites (for example, Facebook). If you give permission for this, the terms of use for those apps/websites apply and you should read them carefully.

It is recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. These applications may run in the background of your device. Mobile apps may have unanticipated impact on the operations of your device (e.g., battery drainage). If you do not have an unlimited data/text plan, you may incur additional charges. At the conclusion of the study, we will provide you instructions on how to remove the mobile apps from your device.

We are not asking you to make any health decisions based on the use of these mobile apps. You should discuss health decisions directly with your healthcare provider.

As with all technology, we ask you to wait until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

Drug and Food Interactions: For your safety, you must tell the study doctor or nurse about all the prescribed medical foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies, and alcohol that you are taking before you start the study and before starting to take any of these products while you are on the study.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
The apps and study medication (NRT) you receive in this study may assist you in quitting smoking. Apps and study interventions are provided at no charge to you. We hope that the information learned from this study will help us develop a finalized version of the LTQ-H app which may help many more smokers living with HIV quit smoking.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
You do not need to participate in this study to get help to quit smoking. If you decide that you do not wish to be a part of the study, the research team will assist you in finding other services or resources that

may be available to you. This may include other popular smoking cessation smartphone apps, and recommendations for NRT use.

Please talk to your doctor about these and perhaps other options.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related laboratory tests and procedures may be reported to The National Institutes of Health and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of The National Institutes on Drug Abuse, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) There is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) You have consented to the disclosure, including for your medical treatment; or
3) The research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).
You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be

destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by 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 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 name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?

If you agree to be in the study, there are no direct costs to you. However, smartphone usage may use some of your cellular data if you are not on WiFi while using the app.
The study team will provide NRT patches free of charge to you. At the end of the study, or if you decide to withdraw from the study before it ends, you may be asked to return all unused study drug.

WHAT ABOUT COMPENSATION?

You will be reimbursed up to $130 for your expenses related to your participation. If you decide to withdraw from the study, you will be compensated for the study activities that you do complete. The compensation scheme for the study is shown below.

Assessment Time Point	Compensation Amount
Screening	$15
Baseline	$15
Week 4	$20
Week 8 (Via telephone)	$30
Week 12	$50
Total	**$130**

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

DUKE UNIVERSITY HEALTH SYSTEM

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DOB: _____

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Pilot Study of a Tailored Evidence-Based Smoking Cessation mHealth App for People with HIV (PWH)

For questions about the study or research-related injury, contact either one of the Principal Investigators:

- Dr. Roger Vilardaga at **919-681-3441** during regular business hours and at **775-303-2103** after hours and on weekends and holidays

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 unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

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. If you do decide to withdraw, we ask that you contact the research team to let them know that you wish to withdraw from the study. You will be asked to complete a termination visit where we will ask you to return any unused NRT, and delete the app off your phone.

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

The study doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if they determine that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. If this occurs, you will be notified and your study doctor will discuss other options with you.

The use of your data may result in commercial profit. You will not be compensated for the use of your data other than what is described in this consent form.

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

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact either one of the Principal Investigators:

- Dr. Roger Vilardaga at **919-681-3441** during regular business hours and at **775-303-2103** after hours and on weekends and holidays

Subject Initials_____

DUKE UNIVERSITY HEALTH SYSTEM

Name: _____

DOB: _____

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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.

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