

CONSENT FORM TO BE PART OF A RESEARCH STUDY

TITLE OF RESEARCH Effectiveness of a Smoking Cessation Algorithm Integrated into HIV Primary Care

IRB PROTOCOL: IRB-300000632

PRIMARY INVESTIGATOR: Karen L. Cropsey, Psy.D.

SPONSOR: National Institute on Drug Abuse

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to test a method of helping people quit smoking. We hope to learn if this method helps people quit smoking. The target enrollment at UAB is 250, with a target of 600 participants across three sites.
Duration & Visits	You will be in this study for 10 months with 5 clinic visits. You will be assessed at the following visits: baseline, 12 weekend of treatment, and 1, 3, and 6 months post treatment.
Overview of Procedures	<p>You will be asked to complete a set of self-report assessments about your smoking history. You will then be randomized to either Group 1 or Group 2. You will be randomly picked (like the flip of a coin) by a computer to be placed in to either group.</p> <p><u>Group 1:</u> Your HIV doctor will receive recommendations for medication to help you quit smoking based on an algorithm (a set of guidelines or rules for making decisions) which is computer-generated and is based on how you answered the questions about smoking. You do not need to take the recommended medication to be part of this study.</p> <p><u>Group 2:</u> Your HIV doctor will not receive these recommendations and you will receive your usual care. Your doctor may or may not offer you medicine to help you stop smoking.</p> <p>The visits should add about 30-45 minutes to your regular clinic visits.</p> <p>Both groups: You will complete a carbon monoxide (CO) test at each visit, along with follow up questionnaires.</p> <p>You will be assessed for 5 study visits at</p> <ul style="list-style-type: none"> • Baseline visit • Week 12 end of treatment • 1, 3, and 6 months after end of treatment visit <p>If you are entered and complete the entire study, you will be in the study for 9 months.</p>
Risks	Risks or discomforts from this research include responding to survey questions that may be sensitive in nature and may make you uncomfortable and risk for a breach of confidentiality

Benefits	You may or may not benefit; however, the results of this study may help us to learn how to improve patient services at this clinic. You will be assigned to a group by chance, which may prove to have more or less benefits than the other study group
Alternatives	Whether to take part in this study is your choice. You do not have to take part in the study and you are free to stop at any time.

Purpose of the Research

You are being asked to participate in a research study to test a method that was designed to help people quit smoking. We hope to learn if this method helps people quit smoking.

Research studies include only people who choose to take part. Please read this consent form carefully and take your time making your decision. If you have any questions, please ask a study staff member to explain any information that you do not clearly understand. We expect that a total of 600 participants will be enrolled in this study: 250 at UAB, 150 at Fenway Health Center in Boston, Massachusetts, and 200 at the University of Washington in Seattle, Washington.

Study Participation and Procedures

As part of your routine assessment on the computer for the CNICS study, you are asked questions about smoking. Based on your responses to these questions, we are asking you to also participate in a study designed to help people quit smoking. If you decide to participate, you will be randomly assigned to one of two groups.

All participants will answer questionnaires on the computer. These questionnaires will ask about your smoking history, your smoking behavior and medication use, nicotine dependence, withdrawal from smoking symptoms, and your thoughts about abstinence. Group 1: Your HIV doctor will receive recommendations for medication to help you quit smoking based on an algorithm (a set of guidelines or rules for making decisions) which is computer generated based on how you answered the questions about smoking. Group 2: Your HIV doctor will not receive these recommendations and you will receive your usual care. Your doctor may offer you medicine to help you stop smoking.

All participants will be referred to standard of care for behavioral support services for cessation (counseling) and will be given a hand-out with tips for quitting smoking. You will also receive 11 weekly brief text surveys in between your baseline and 12 weekend of treatment visit. Standard text messaging fees will apply. This research study and the University of Alabama at Birmingham are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts. We will ask you to sign a release of information so that we will have access to your HIV biomarkers.

After your initial visit, you will have a 12 weekend of treatment visit. Follow-up study visits occur at 1-, 3-, and 6-months post-treatment. At these visits you will be asked to complete a few more questionnaires than you usually complete at the clinic visit. If you do not come to clinic, you will be either sent a link via e-mail to complete the questionnaires or complete them over the phone with study staff. For study visits where you are in clinic, you will have a carbon monoxide (CO) test where you will blow into a machine (like an alcohol breathalyzer) which will tell us how much CO is in your lungs as a result of smoking. Each study visit will add about 30- 45 minutes to your usual clinic visit.

Study Assessment Schedule	BASELINE		Follow-up			
			Wk 12 (EOT)	1 MO F/U	3 MO F/U	6 MO F/U
Compensation Schedule	\$20	RANDOMIZED CONTROL	\$40	\$40	\$40	\$50
Consent	X					
Physician Prescription	X					
Medication Checks						
Additional Medication Added						
Brief Counseling	X					
Viral load; CD4	X					X
Side Effects	X		X	X		
CO	X		X	X	X	X
Demographics	X					
CNICS assessments	X		X			X
Smoking Behavior/Med Use Questionnaire	X		X	X	X	X
Smoking History Questionnaire	X					
Questionnaires: Fagerstrom Test for Nicotine Dependence (FTND), Questionnaire of Smoking Urges Brief Form (QSU), Hughes-Hatsukami Withdrawal Scale (HHWS), Thoughts about Abstinence (TAA)	X		X	X	X	X

In addition to your scheduled study visits, we call you weekly to complete a brief survey for the 11 weeks between your Initial Visit and your End of Treatment Visit. These weekly surveys will each take approximately 15 minutes to complete.

Any medications to treat smoking that may be prescribed or other medical services that may be provided as part of a treatment plan for your smoking will be part of your usual clinical care. However, you will receive a call from research staff two weeks after beginning smoking cessation medication to check on your medication. Your clinical information regarding any smoking cessation pharmacotherapy your provider prescribes will be gathered during the time of the study, coded, and included in the database. You will be asked to allow study staff to look at your medical records. These records will be reviewed for information related to your health care visits such as treatment history and laboratory tests.

We will also review your records to obtain contact information in case the study staff needs to contact you for any reason. We are also requesting your permission to use your data from your electronic medical record and the CNICS study, including the questions you answer via touch screen computer at the start of your visit.

Risks and Discomforts

Physical: The use of pharmacotherapy to treat smoking cessation is considered standard of care. This study may provide a recommendation to your doctor regarding which medication to use, but the effectiveness of each is not within the scope of the study. Side effects will be monitored by the providers during the patient's regular clinic visit and will be recorded as part of the research session. Quitting smoking is associated with withdrawal symptoms including increased appetite, irritability, insomnia, depressed mood, and cravings.

Psychological: As with other interventions with a behavioral/psychological component, some participants may be uncomfortable answering personal questions on questionnaires or talking about personal information during a clinic visit. Quitting smoking is difficult, and participants may feel frustrated or upset if they are not able to quit smoking. Further, quitting smoking and withdrawal may cause feelings of depression or irritability should your doctor choose to provide you medication to help you stop smoking, you should discuss the risks and benefits of your treatment plan with your doctor. As medications to treat smoking cessation may have side effects or interact with other drugs you are taking, make sure you tell your doctor about all the prescription drugs, herbal products, over-the-counter (OTC) drugs, vitamins and natural remedies that you are taking. These risks and benefits are **not specific to this research study** but may be part of the treatment that you and your doctor will decide on for your smoking.

There is the risk of loss of confidentiality, but we will take every precaution to protect your confidentiality.

You will be assigned to a group by chance, which may prove to be less effective or to have more side effects than the other study group or alternatives.

Information for Women of Childbearing Potential, Nursing Mothers, and/or Men Capable of Fathering a Child

Some medications may have additional risks when taken during pregnancy or breastfeeding and may also influence sperm production. These risks are not specific to this research study but may be part of the treatment that you and your doctor will decide on for your smoking use. Women who desire to become pregnant or men who may father a child should discuss with their doctor the risks of any medicines before starting the medicine. If you become pregnant, Dr. Cropsey, one of her colleagues on the study or your clinic doctor may decide it is in your best interest to take you out of the study. This will not affect your routine clinic visits.

Benefits

You may or may not benefit by being in the study; however, the results of this study may help us to learn how to improve patient services at this clinic.

Alternatives

One alternative is always possible: you can choose not to participate in the study and, instead, receive routine treatment. Participating or not participating in the study will not prevent your treatment here or at any other agency where you seek treatment.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- The UAB Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- National Institutes on Alcohol Abuse and Alcoholism (NIAAA)
- Our collaborators at the University of Washington and the Fenway Health Center

The information from the research may be published for scientific purposes; however, your identity will not be given out.

Information obtained during the course of the study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself, or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

Only a code number, not your name, will be used to identify your information on study materials, including lab specimens. This will be maintained in a password-protected computer database on a secure server within the UAB 1917 Clinic, the Bevell Biomedical Research Building (BBRB), and study staff offices. Any paper materials linking your name and code number will be kept in locked filing cabinets in locked offices of study personnel on a need-to-have basis. Your study materials will be maintained for a period of three years after the conclusion of the study. At that time the research information not already in your medical record will be destroyed.

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?

All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be

in your medical record.

A description of this clinical trial will be available on www.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.

Who may use and give out information about you?

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?

All Individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections(OHRP)
- the U.S. Food and Drug Administration(FDA)
- Department of Health and Human Services (DHHS)agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, University of Alabama Health Services Foundation, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the UAB IRB and its staff
- the billing offices of UAB and UAB Health Systems affiliates and/or Children's of Alabama and its billing agents

Why will this information be used and/or given to others?

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute on Drug Abuse (NIDA) which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you 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.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

What if I decide not to give permission to use and give out my health information?

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?

You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?

Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to Dr. Karen Cropsey, 1670 University Blvd. Volker Hall, Suite L107, Birmingham, AL 35233. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?

If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal

Taking part in this study is your choice. There will be no penalty if you decide not to be in the study and you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution.

You may be removed from the study without your consent if the sponsor ends the study, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study. The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner. Any smoking cessation study drug copays or drug cost not covered by your insurance will be covered by the study.

Payment for Participation in Research

You will be paid \$20 for the baseline visit, \$40 each for Week 12 end of treatment, 1, and 3 month follow-up visits, and \$50 for the 6 month follow-up visit. If you withdraw from the study, you will be paid for each study visit made to the clinic. The total payment you may receive is \$190. If you do not finish the entire study, you will be paid at the time you decide to stop taking part in the study. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

Payment for Research-Related Injuries

UAB and NIH have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge. The cost for that medical care will be billed to you or your insurance company, just as for other medical care.

Significant New Findings

You will be told by your doctor or the study staff if new information becomes available and might affect your choice to stay in the study.

Optional

Text Message Surveys

We would like to send you brief surveys via text message that will ask about your smoking cessation medication use. These texts will be sent weekly between your baseline visit and your 12 week follow-up visit. The text messages will contain no personal health information (PHI). The surveys will be completed on a HIPAA compliant platform, Qualtrics.

Initial your choice below:

_____ I agree to receive weekly text messages (11 total) from study staff.

_____ I do not agree to receive weekly text messages (11 total) from study staff.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact Drs. Karen Cropsey or Ellen Eaton. They will be glad to answer any of your questions. Dr. Cropsey's number is 205-975-4204. Dr. Eaton's number is 205-975-0661. She may also be reached after hours by paging her at 205-934-3411.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the Office of the IRB (OIRB) at (205) 934-3789 or toll free 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures

Your signature below indicates that you agree to participate in this study. You will be offered a signed or unsigned copy of this document.

Printed name of Participant

Signature of Participant

Date

Printed Name of Person Obtaining Informed Consent

Signature of Person Obtaining Informed Consent

Date