UNIVERSITY OF PENNSYLVANIA
RESEARCH STUDY SUMMARY FOR POTENTIAL SUBJECTS

Protocol Title:	**Understanding the Role of Cognitive Dysfunction in the Treatment of Nicotine Dependence (IRB# 824860)**
Principal Investigator:	**Rebecca Ashare, Ph.D., Phone: 215-746-5789** **Department of Psychiatry, University of Pennsylvania**
Emergency Contact:	**Frank Leone, M.D., Phone: 267-239-3651** **University of Pennsylvania**

You are being invited to participate in a smoking cessation research study. Your participation is voluntary and you should only participate if you completely understand what the study requires and the risks of participation. You should ask the study team any questions you have before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact either, the Penn Institutional Review Board (IRB) at (215) 898-2614, or the Research Participant Coordinator at the Philadelphia Department of Public Health IRB at (215) 685-0869 for assistance.

The main purpose of this research study is to examine how not smoking for a short period of time (24 hours) affects performance on computer tasks. You are being asked to take part because you are a smoker, have expressed an interest in quitting, and meet other program criteria.

If you agree to join the study, you will be asked to complete tasks to determine your eligibility, either in-person or remotely by phone/video call. If you are deemed eligible to participate you will be asked to complete 9 additional sessions. This includes 2 visits where you will complete computer tasks, 6 smoking cessation counseling sessions and 1 follow-up session. Within the week of your first counseling session, you will receive nicotine patches (Nicoderm CQ) and be instructed on how to use them.

Your participation in the study will last approximately 4 months. If you are deemed eligible you will be given a study schedule that outlines your scheduled sessions.

If enrolled in this study, you may benefit from knowing that you are contributing to the advancement of treatments to help people quit smoking. The smoking cessation counseling and nicotine patches may also help you make a successful quit attempt.

The most common risks of study participation are potential side effects from the nicotine patch. These side effects tend to be mild, and include: nausea, dizziness, rapid heartbeat, increased blood pressure, rash and/or itching, redness at patch site and/or minor swelling, difficulty sleeping and weird dreams. You will be monitored for side effects throughout the study.

The alternative to participation in this program is to decide not to participate. If you do not wish to enroll in this study and still wish to seek assistance with quitting smoking, we can provide information on other quit smoking studies at our center or other treatment programs located in the Philadelphia area.

Please note that there are other factors to consider before agreeing to participate in this study, such as additional procedures, use of your personal information, and other possible risks. If you are interested in participating, a member of the study team will review the full study information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA FORM

Protocol Title:	**Understanding The Role Of Cognitive Dysfunction In The Treatment of Nicotine Dependence (IRB# 824860)**
Principal Investigator:	**Rebecca Ashare, Ph.D., Phone: 215-746-5789** **Department Of Psychiatry, University Of Pennsylvania**
Emergency Contact:	**Frank Leone, M.D., Phone: 267-239-3651** **University Of Pennsylvania**

WHY AM I BEING ASKED TO VOLUNTEER? You are being asked to take part in a smoking cessation research program because you are a smoker, have expressed an interest in quitting, and meet other program criteria. Your participation is voluntary which means you can choose whether or not to participate. Before you make this decision, you will need to know the purpose of the research program, the possible risks and benefits of being in the research program, and what you will have to do if you decide to participate. The research team is going to talk with you about these things today. Please ask them to explain anything you do not understand, including any language contained in this form.

You do not have to make a decision about participating in this research program today; you can request a copy of this form to review at a later time, or share it with your family, friends, and/or doctor. Whatever you decide, there will be no loss of benefits to which you are otherwise entitled. If you do decide to participate, you will be asked to sign this form and will be given a copy for your records.

WHAT IS THE PURPOSE OF THIS RESEARCH STUDY? The main purpose of this research study is to examine how not smoking for a short period of time (24 hours) affects performance on computer tasks.

HOW LONG WILL I BE IN THE STUDY? HOW MANY OTHER PEOPLE WILL BE IN THE STUDY? Overall, 300 people will complete this research program over a 5.5-year period. Your individual participation will last about 4 months.

WHAT AM I BEING ASKED TO DO? Your participation in this research program will first involve reviewing the study's informed consent/HIPAA form, where you will hear a description of the program. If you are interested in participating after hearing the description and having your questions answered, you will be asked to sign this form and then complete tasks to determine your eligibility for the study. These tasks make up the Intake session, and some may take place remotely. The Intake session is necessary to make sure it is safe for you to participate. If you are eligible to participate after the completion of these tasks, you will be asked to complete 9 additional sessions over a 4-month period. Some of these sessions may be completed by phone, and as a result some study material may be mailed to you. You will also be asked not to use any smoking cessation therapy other than that which is provided to you as part of this study. Study visits are described in more detail below.

Intake Session. Tasks listed below that can be completed remotely will be done by phone/video call to reduce the length of in-person tasks. The in-person tasks will last about 1-1.5 hours. You will be asked to:

- Provide a urine sample (at least 30mL [two tablespoons]) for drug and (if applicable) pregnancy tests. If you test positive for any of the following drugs: cocaine, amphetamines, methamphetamines, PCP, barbiturates or ecstasy (MDMA), you may not be eligible to participate in this study. Results from this testing are used for research purposes only and will not be shared with you. You will be informed of your eligibility status after testing, but specific results will not be shared. Some (at least 8mL) of the urine collected for drug screen may be stored for analysis of nicotine metabolites. If we are unable to store the sample at Intake, we may attempt to do so at a later time point. You will not receive the results or feedback from this analysis.
- **(Females of child-bearing potential only):** Be provided with a urine pregnancy screen and will be asked to perform the screening independently. For safety purposes, if you think you are pregnant, we advise

that you discontinue study participation. There is no penalty for withdrawing from the study at this point and you will still receive travel reimbursement.

- Provide a breath sample for a carbon monoxide (CO) assessment to confirm prior exposure to cigarette smoke. Carbon monoxide is a poisonous gas that comprises less than 1% of the air we breathe and is a product of cigarette smoking.
- Complete brief psychiatric assessments called the 'MINI' and 'CSSRS' interviews. During these interviews, we will ask you about any current and past depressed mood symptoms, as well as other psychiatric symptoms.
- Complete a medical history, blood pressure assessment, and be asked about any medications that you are currently taking or discontinued taking within the last 2 weeks.
- Complete a brief mental ability test called the 'Shipley Institute of Living Scale'.
- Complete assessments of your demographics, alcohol and smoking history, smoking rate, behaviors, and mood.
- Complete a survey that asks about your experiences during the COVID-19 pandemic. You will be asked to provide verbal consent for the recording of this survey before it is administered.

You may be asked to complete a rapid HIV blood test using a drop of blood drawn by a small finger prick (similar to a blood sugar test) to confirm your HIV status. The test will be administered by a trained professional and will take approximately 20 minutes to process.

If you are eligible following these tasks, you may be asked to provide two tubes of blood (less than 2 tablespoons). The first sample will be used to determine your nicotine metabolite ratio (NMR). The 2nd tube of blood will be used to determine biomarkers of inflammation. Because this is experimental and we do not yet understand the role of NMR and inflammation in smoking behavior, you will not receive the results or feedback from this analysis.

You will also schedule two laboratory sessions. You will also be told at this time whether your first lab session is the smoking as usual session or the 24-hour abstinence session. Due to the popularity of this study, after the study schedule has been created, participants will only be permitted to reschedule one appointment.

Laboratory Session 1. These in-person tasks will last about 1-1.5 hours. You will be asked to:

- Provide a urine sample (at least 30mL [two tablespoons]) for drug and (if applicable) pregnancy tests. If you test positive for any of the following drugs: cocaine, amphetamines, methamphetamines, PCP, barbiturates, or ecstasy (MDMA), you may not be eligible to participate in this study. Results from this testing are used for research purposes only and will not be shared with you. You will be informed of your eligibility status after testing, but specific results will not be shared.
- Provide a breath sample for a carbon monoxide (CO) assessment.
    - If this is your smoking session: You will smoke one of your own brand cigarettes at the beginning of the session.
    - If this is your abstinent session: Your readings must be less than 10ppm or less than 50% of the CO reading taken at Intake; if your readings are higher, you may be withdrawn from the study.
- Complete a blood pressure assessment.
- Complete questionnaires that assess smoking behavior, mood, and sleep quality.
- Complete computer tasks that test your memory and attention.

Laboratory Session 2. The second laboratory session will be identical to Lab Session 1 except you will complete the alternative smoking condition (e.g., if you were asked to stop smoking before Lab Session 1, you will be asked to smoke as usual for Lab Session 2).

- You will be provided with an iCO monitor (carbon monoxide reader) and will be instructed on how to use it. You will be asked to use this device to measure and report your carbon monoxide levels for the counseling and follow-up sessions.

    - The device connects to a smartphone or tablet and uses an app that you would download to display readings. If you are unable to use this device and you report not smoking following the Pre-Quit session, you may be asked to come to our center to complete the carbon monoxide assessment.
    - This device is intended for single use as it cannot be sanitized. We will ask that you not share the device with friends or family to reduce the risk of contamination.
- You may receive a binder containing all information necessary for your counseling sessions. Please keep this binder safe as it will be referenced during your counseling sessions to help guide you during your quit smoking attempt. If preferred, this paperwork may also be mailed or emailed to you.

After you complete the two laboratory sessions, you will begin your treatment plan at your "Pre-Quit" visit. All participants will take part in the same smoking cessation counseling program, which consists of individual counseling and nicotine replacement therapy (NRT) with nicotine patches (Nicoderm CQ®).

Pre-Quit Visit. This session will primarily be completed by phone/videocall and will last about 1.5 hours. During this time, you will:

- Measure your carbon monoxide level using the iCO monitor (if provided) and report the reading to staff.
- Complete smoking rate assessments and questionnaires that assess smoking behavior and mood.
- Receive instructions on how to use your supply of nicotine patches, which will be mailed to you within a week of this visit. You will also review safety information and emergency contact numbers for the study physician, which will be included with your patches.
- Take part in a one-hour standardized smoking cessation counseling session to help prepare you for your upcoming quit attempt. You will set your Target Quit Date (TQD) with your counselor.

Target Quit Date (TQD). On your Target Quit Date, you will speak with a smoking cessation counselor and complete a 30-minute "quit-day" session to review your initial quit attempt, identify potential reasons for relapse back into smoking, and review a plan for avoiding tempting situations. This visit will be completed by phone/videocall and will last about 1 hour. In addition to counseling, you will:

- Measure your carbon monoxide level using the iCO monitor (if provided) and report the reading to staff. If you report abstinence and are not able to use the iCO monitor, you may be asked to come to our center for CO verification.
- Complete questionnaires that assess smoking behavior, mood, and sleep quality.
- Complete side effects, smoking rate, and nicotine patch use assessments.

Beginning on your TQD, if you smoke 10 or more cigarettes per day you will use the 21mg patch for the first 4 weeks, 14mg patch for the following 2 weeks, and the 7mg patch for the final 2 weeks. If you smoke 5-9 cigarettes per day you will use the 14mg patch for the first 6 weeks and the 7mg patch for the final 2 weeks.

Mid-Treatment Assessments. Following your TQD, you will speak with a smoking cessation counselor to complete four in-person booster counseling sessions by phone/videocall at Weeks 5, 6, 7, and 8. These sessions will last between 30 minutes and 1 hour and will focus on either reinforcing your success and reviewing your quit plan or reestablishing another quit date and restarting the smoking cessation process. You will also be asked to:

- Measure your carbon monoxide level using the iCO monitor (if provided) and report the reading to staff. If you report abstinence and are not able to use the iCO monitor, you may be asked to come to our center for CO verification.
- Complete questionnaires that assess smoking behavior and mood.
- Complete side effects, smoking rate, and nicotine patch use assessments.

In total, you will receive up to 6 smoking cessation counseling sessions. Sessions may be audio-taped to ensure the treatment is consistent for all participants. Audio recordings will be saved on password-protected computers and deleted at the end of the study.

Follow-Up. Finally, at Week 12 you will be asked to complete a 30-45 minute session, where you will:

- Measure your carbon monoxide level using the iCO monitor (if provided) and report the reading to staff. If you report abstinence and are not able to use the iCO monitor, you may be asked to come to our center for CO verification.
- Complete questionnaires that assess smoking behavior, mood, sleep patterns and social support.
- Complete side effects, smoking rate, and nicotine patch use assessments.

Viral Load and Anti-Retroviral Information. If you are HIV+, we will ask that you complete a questionnaire about your anti-retroviral use at each study visit. As part of the Intake session, and around Week 8, we will ask you to provide viral load results and may contact your clinic or provider for this purpose. In order to collect this information, we may ask you to review and sign a HIPAA short form for the release of this information for the research study.

End of Study Phone Call (within a week of last completed visit). Participants will be contacted within a week of their last completed visit for the study. This call will be to discuss any final details of participation and to answer any questions the participant may have.

HOW WILL I RECEIVE COMMUNICATIONS FROM THE STUDY? As discussed during your initial phone screening, the primary mode of communication throughout the study will be text via the Way 2 Health software platform. You will be contacted up to several times a week with study reminders and 3 times throughout the study for short text-based surveys. You may change your communication preference at any time during the study. If you do not wish to receive text reminders or if you do not have a phone that is compatible with text reminders, you can opt to receive phone call or email reminders.

Visit Reminders. Two weeks prior to your final visit (Week 12), you may also receive a reminder to fade down to the 7mg nicotine patch for your last two weeks of treatment.

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS? While enrolled in this research program, you will be asked not to use any smoking cessation therapy other than that which is provided to you as part of this study. You will be asked not to use other treatments for nicotine dependence, including Chantix®**,** nicotine gum, nicotine spray, nicotine lozenge, nicotine inhaler and the e-cigarette. The likelihood and severity of the potential risks to you are described below:

Nicotine Replacement Therapy (NRT): In general, the nicotine patch is tolerated well by those who use it. Although the nicotine patch delivers nicotine (the addictive ingredient in cigarettes), it is at a lower level than the nicotine delivered when smoking a cigarette. Thus, the level of nicotine in your body from using the nicotine patch is lower than if you were smoking. There is no evidence of addiction to the nicotine patch when used as part of a comprehensive smoking cessation program such as this one. Using the nicotine patch is less harmful to your health than cigarette smoking.

The most frequent side effects reported by those using NRT are listed below. These side effects tend to be mild.

- Nausea
- Dizziness
- Rapid Heartbeat
- Increased blood pressure
- Rash and/or itching
- Redness at the patch site and/or minor swelling
- Difficulty sleeping
- Weird dreams

Symptoms of an allergic reaction may include difficulty breathing or rash. We will closely monitor your side effects or medical concerns throughout the study. Any notable side effects or medical concerns will be presented to the Study Physician for instructions on how to best proceed with your treatment.

To minimize skin reactions, you should move the site of patch placement each day. Some people report difficulties sleeping or vivid dreams; however, this can be alleviated by removing the patch when you are sleeping and

reapplying a new patch in the morning. To avoid possible burns, you should also remove the patch before undergoing any MRI procedures. In some cases, nicotine patch use may delay wound healing and may contribute to the risk of peptic ulcer formation.

Other side effects listed occur rarely and are most often caused by continuing to smoke while using the patch. Rarely, smokers may experience vomiting, diarrhea, or weakness when using the patch. If these reactions occur, you can call the emergency contact (Study Physician) listed on page 1 of this form, members of the study team, and your doctor. You should always report any negative reactions you believe may be caused by the patch to the study team. If these reactions occur as a consequence of concurrent patch and tobacco use, you may be asked to stop using the patch, reestablish the quit day, and restart cessation attempts. We will not require that you remove the patch if you return to smoking, unless you are experiencing side effects that concern you. Instead, we will advise that you continue to wear the patch and work with your counselor to try to quit smoking again. Counselors have been specially trained to handle smoking relapse and to help prepare you for an additional quit attempt if necessary.

Another possible side effect of regular smoking while wearing the patch is high blood pressure. If you present with a blood pressure of greater than 160/100 (either number) at the Intake or Lab sessions, you may be asked to obtain written permission from your personal physician to receive them. Please note, if you are unable to receive patches you may still continue with the remainder of the study and receive all cessation counseling as scheduled.

A stringent list of exclusionary criteria will be employed to further limit the possibility of the side effects listed above. You should still inform your doctor that you are using the nicotine patch because it can increase your heart rate and blood pressure. You should not stop using the patch without discussing your symptoms with the Study Physician and study staff.

Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away. Dispose of the used patches by folding the sticky ends together, then placing it in the pouch.

Reproductive Risks (**Females only)**: The safety of nicotine replacement therapy for an unborn baby is unknown, so females of childbearing potential should not become pregnant, or nurse a baby, while in this study. If you are currently pregnant or breast feeding, you should not participate in this study. If you are a woman of childbearing potential, you must use an adequate form of birth control or abstain from sexual intercourse for the duration of the study. Adequate forms of birth control include diaphragm, cervical cap, condom and spermicide, surgical sterility, or birth control pills. If you become pregnant during the study, you should notify the research staff immediately. You may be asked to stop using the nicotine patch but may remain in the study and receive counseling only. All female participants of child-bearing potential will complete a pregnancy test at the Intake, Lab 1 and Lab 2 sessions.

Assessments, including Smoking Cessation Counseling: Some people can experience anxiety and other types of general distress when they complete questionnaires and take part in smoking cessation counseling sessions. This is generally related to your feelings about quitting as well as learning about some of the health risks associated with smoking. These reactions are usually very mild and typically diminish with time. The staff is trained to help you should you experience any concerns.

Withdrawal Syndrome: Most individuals who quit smoking experience symptoms of withdrawal. These symptoms can occur almost immediately and last for about 10-14 days. These feelings include:

- Sadness & mood changes
- Constipation
- Irritability
- Anger
- Restlessness & nervousness
- Appetite increase & weight gain
- Insomnia
- Decreased heart rate
- Craving for nicotine
- Difficulty concentrating
- Anxiety
- Muscle pain
- Headaches

Your smoking cessation counselor will work with you to develop strategies to help you deal with any withdrawal symptoms that you may experience. If you feel that your withdrawal symptoms are not lessening over time and are significantly interfering with your ability to function, you should contact the Emergency Contact listed on page one of this consent form.

Blood draw: Blood draws may result in bruising and/or slight bleeding at the needle site or may cause you to feel faint. All of these side effects are rare. Blood will be drawn by a trained professional, reducing the risks of these discomforts.

HIV Testing: If you are asked to complete the rapid HIV blood test, testing may result in mild pain from the finger stick and feelings of anxiety about test results. These tests will be administered only by a trained professional to reduce the risk of these discomforts.

WHAT IF NEW INFORMATION BECOMES AVAILABLE ABOUT THE PROGRAM? During the course of this program, we may find more information that could be important to you and your health. When feasible, we will notify you as soon as possible if such information becomes available. For example, we would contact you immediately if new information became available about the study medication that might cause you to change your mind about being in the program.

WHAT ARE THE POSSIBLE BENEFITS OF THE PROGRAM? Participants who enroll in this trial may benefit from the knowledge that they are contributing to the advancement of the treatment for smoking cessation. All participants will receive smoking cessation counseling and nicotine patches which can help them make a successful quit attempt.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT PARTICIPATE? The alternative to participation is to decide not to enroll in this program. If you do not wish to enroll in this program and still wish to seek assistance with quitting smoking, we can provide you information on other quit smoking studies at our center or other treatment programs located in the Philadelphia area.

WILL I BE PAID IN THIS PROGRAM? To reimburse you for the time and effort needed for completing assessments, you may earn up to $380, which includes $10 for travel-related expenses. In place of $10/session to cover travel expenses, you may elect to use a round-trip car ride service (i.e., Lyft) which will be arranged and paid for in full by the research study. If you choose to use the ride service, you will not receive $10 for your travel reimbursement. For visits following the Lab sessions, you may only be reimbursed for travel if you come to our center for carbon monoxide verification after reporting abstinence. Travel will not be reimbursed for sessions completed entirely by phone.

The “task completion” compensation will depend on you arriving on time for in-person visits and following study instructions. If you do not follow study instructions, the task completion compensation may be withheld.

The Greenphire ClinCard will be the primary form of payment for this study. The ClinCard is a reloadable, pre-paid card for the purposes of compensation. Compensation will be loaded onto the ClinCard within 24 hours of completed visits. Staff may ask you to provide a Social Security Number, or complete a W-9 for this purpose, after determining your eligibility so that a ClinCard can be assigned to you. Clincards may be mailed to you following your eligibility determination for the study.

If you are deemed ineligible at any point during the study (including after Intake tasks), you will only be compensated $10 to cover travel costs for in-person visits, unless you have elected to use the ride service.

You may also receive a $20 bonus for each person successfully referred to the program, for a maximum of three referrals. This bonus will be paid once your participation has ended (Week 12).

The payment schedule is as follows:

Week	Study Visit	Visit Compensation	Task Completion	Travel[2]	Bonus	Total
0	Intake	$20	--	$10		$30
1	Lab 1	$40	$10	$10		$60
2	Lab 2	$40	$10	$10		$60
3	Pre-Quit Visit	$20	$10	–		$30
4	Clinic Visit (TQD)	$20	$10	–		$30
5	Clinic Visit	$20	$10	–		$30
6	Clinic Visit	$20	$10	–		$30
7	Clinic Visit	$20	$10	–		$30
8	Clinic Visit	$20	$10	–		$30
12	Follow-Up (EOT)	$40	$10	–		$50
				Study Total:		$**380**
N/A	Referral Bonus				$60[1]	$60
				Total w/ Referrals		**$440**

[1]Table shows compensation for three successful referrals ($20/each)
[2]Only paid if you opt-out of the round-trip car ride service for in-person visits; will be paid if you are asked to come to our center to verify abstinence for clinic visits or follow-up.

HOW DOES TRAVELING VIA THE RIDE SERVICE WORK? You may elect to use "Roundtrip", which is a car ride service that collaborates with Lyft to coordinate round-trip rides to study appointments. Study staff will schedule each ride using your first name, last name, and phone number via Roundtrip's HIPAA compliant platform. You will receive a reminder call 24-48 hours prior to your visit to confirm your visit, interest in using the ride service, and preferred pickup/drop-off locations. If the study staff cannot reach you by 5pm the day prior to your visit, your ride will be cancelled. You will still be permitted to attend the visit and will receive $10 to cover your travel expenses. If you need to cancel a previously confirmed ride, you must do so by contacting the study staff immediately, preferably by 5pm the day before your appointment. If you fail to notify study staff within this timeframe, you may no longer be permitted to use the ride service at future study visits.

WILL I HAVE TO PAY FOR ANYTHING? There will be no charge to you for participating in this research program. You will also receive the quit smoking counseling and nicotine patches at no cost. You and/or your health insurance may be billed for the costs of medical care during this program if these expenses would have happened even if you were not in the program or if your insurance agrees in advance to pay.

If you choose to receive text message reminders, you will be responsible for the costs associated with the receipt of these text messages. For example, if you have a monthly text-messaging plan, these messages will count towards your monthly text-messaging total. If you do not have a plan, you will be charged the standard text messaging fees by your wireless provider. You may receive a maximum of 20 text messages from the study each month.

WHAT HAPPENS IF I AM INJURED OR HURT IN THE RESEARCH PROGRAM? In the event that you are hurt or injured as a result of participation in this research program, please contact the investigators listed on page one of this form. We will offer you the care needed to treat injuries directly resulting from participation in this research program. We may bill your insurance company or other third parties, if appropriate, for the costs of the care associated with these injuries; however, you may also be responsible for some of these costs. There are no plans for the University of Pennsylvania to pay you or provide other compensation for the injury. You do not give up your legal rights by signing this form.

WHEN IS THE RESEARCH PROGRAM OVER? CAN I LEAVE BEFORE IT ENDS? This research program is expected to end after all participants have completed all visits and all information has been collected. This program may also be stopped at any time by your physician, the program Sponsor, or the Food and Drug Administration (FDA) without your consent if:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you would be informed if such a decision was made and the reason for this decision.
- You have not followed program instructions.
- The Sponsor or Principal Investigator has decided to stop the program.

If you decide to participate, you are free to leave the research program at any time. Withdrawal will not interfere with your future care or participation at our center.

WHAT HAPPENS TO MY COLLECTED SAMPLES AND INFORMATION? Samples (urine and blood) collected as part of this study will be used to analyze biomarkers of smoking and inflammation. We would like to store your information (such as demographic information, smoking behavior, and questionnaire responses) and samples for possible use in future research. This storage may be for an indefinite amount of time. The information and samples you provide may be shared with other research institutions, e.g. The Abramson Cancer Center at Penn, or researchers working with the NIH who want to learn more about nicotine addiction and/or better ways to help people quit smoking. Whole genome sequencing will not be conducted on your samples. Whole genome sequencing involves analysing your entire personal genetic code.

We will protect your confidentiality by first labeling your information and samples with an identification number only (not your name). We will restrict access to the databases that hold your personal information. Your samples will be stored in a locked, private bank, which only authorized personnel will have access to. Permission to store your information and samples for use in future research is optional and you can indicate your choice at the end of this consent form. You may withdraw your permission at any time by contacting study staff and letting us know you no longer want your information and samples to be stored for use in future research. Your samples may be used to create products, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family. Most use of samples or information do not lead to commercial products or to profit for anyone. Additionally, we will not follow up with you about the specific research that will be done, and individual research results obtained as part of future research will not be shared with you.

WHO CAN SEE OR USE MY INFORMATION? HOW WILL MY PERSONAL INFORMATION BE PROTECTED? While we cannot guarantee total privacy, we will do our best to make sure that the personal information in your research record is kept private. We will store your information in a secure room with limited access. We will control access to the computer files that hold this information. Your personal information would only be given out if required by law. If information from this research is published or presented at scientific meetings, your name and other personal information will not be used. We will identify your test results with an identification number only (not your name). Only authorized program personnel will be able to link your identification number with your name. Your samples will be stored in our private bank, which can be accessed only by authorized study personnel. If you tell us that you are involved in a situation of child abuse or that you are going to harm yourself, we will have to break confidentiality and report this to local authorities as required by law.

WHAT INFORMATION ABOUT ME MAY BE COLLECTED, USED OR SHARED WITH OTHERS?

- Name, address, telephone number, email address
- Date of birth
- Social Security Number (W-9 form)
- Some personal information that may be considered sensitive, such as medical history, psychological history, alcohol use history, etc.
- Results from physical examinations, tests or procedures, including urine drug screening
- Information on smoking, cognition, or inflammation biomarkers from the blood and urine samples provided at the Intake Session
- Medical Record Number
- Results from HIV testing (if applicable)

WHY IS MY INFORMATION BEING USED? Your personal contact information is important for the research team to

contact you during the program. Your personal health information and results of procedures are being collected as part of this research program. In some situations, personal health information might be used to help guide your medical treatment.

WHO MAY USE AND SHARE INFORMATION ABOUT ME? The following individuals and organizations may use or disclose your personal health information for this research program:

- The Principal Investigator (PI) and research collaborators
- The University of Pennsylvania Institutional Review Boards (the committees charged with overseeing research on human subjects) and the University of Pennsylvania Office of Regulatory Affairs
- The University of Pennsylvania Office of Clinical Research (the office that monitors research studies)
- Way 2 Health team (programming, troubleshooting, monitoring software etc.)
- Authorized members of the University of Pennsylvania, UPHS, and School of Medicine workforce that may need to access your information in the performance of their duties (e.g., research oversight and monitoring)

ELECTRONIC MEDICAL RECORDS AND RESEARCH RESULTS

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record. If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.). No results from this research study or analyses will be placed in your EMR.

WHO, OUTSIDE THE SCHOOL OF MEDICINE, MIGHT RECEIVE MY INFORMATION?

The following University department is working with the Principal Investigator:

- Center for AIDS Research (CFAR), University of Pennsylvania

The following are supporting and overseeing the research and the sponsor:

- The Food and Drug Administration
- The National Institutes of Health (NIH)
- The Abramson Cancer Center, University of Pennsylvania
- Philadelphia Department of Public Health Institutional Review Board

The following entity is managing participant transportation and has access to first name, last name, and phone number only:

- Roundtrip

If you receive an HIV test as part of this study, by law we have to report your HIV infection (if you test positive) to the City of Philadelphia Health Department. We would report your name, gender, racial/ethnic background, and the month and year you were born. This is to keep track of how many people in the U.S. have HIV infection. It is also to make sure that states get enough money from the federal government to support the medical care of people living with HIV. The Health Department does not share the names of HIV infected people with anyone else. It removes all personal identifiers, such as your name, before giving information on the number of HIV infections to the federal government.

The Principal Investigators or research staff will inform you if there are any changes to the list above during your active participation in the trial. Once your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations. This does not mean that all personal identifying information is being disclosed. Generally, if information has to be released it contains only initials and birth date, or only a unique number, not complete contact information. Any such additions will be subject to Penn UPHS and School of Medicine procedures to protect your privacy.

HOW LONG MAY THE SCHOOL OF MEDICINE USE OR DISCLOSE MY PERSONAL HEALTH INFORMATION (PHI)? Your authorization for use of your personal health information for this specific program does not expire. Your information may be held in a research repository or database. However, UPHS and the School of Medicine may not re-use or re-disclose information collected in this program for a purpose other than this program unless:

- You have given written authorization to do so
- The University of Pennsylvania Institutional Review Board grants permission after ensuring that appropriate privacy safeguards are in place
- As required by law

CAN I CHANGE MY MIND ABOUT GIVING PERMISSION FOR USE OF MY INFORMATION? You may withdraw or take away your permission to use and disclose your health information at any time. You do this by contacting study staff or sending written notice to the investigator for the program. If you withdraw your permission, you will not be able to stay in this program.

WHAT IF I DECIDE NOT TO GIVE PERMISSION TO USE AND GIVE OUT MY HEALTH INFORMATION? You will not be able to participate in this research program.

WHO CAN I CALL WITH QUESTIONS, COMPLAINTS 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 program or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached, or you want to talk to someone who is not directly involved with this program, you may contact the Office of Regulatory Affairs with any questions, concerns, or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research program. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the operations of this study. A copy of this form will be given to you.

Name of Research Participant:

PRINT NAME: _____

SIGNATURE: _____ DATE: _____

Name of Person Obtaining Consent:

PRINT NAME: _____

SIGNATURE: _____ DATE: _____

Future Use Of Data/Biospecimens:
Please initial and check **YES** if you give permission for us to store your information and samples from this study for use in future research. Please initial and check **NO** if you **do not** give us permission to store your information and samples from this study for use in future research.

☐ YES ☐ NO Participant Initials: _____