UNIVERSITY OF PENNSYLVANIA
COMBINED SUBJECT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	The Effects of IQOS Use on Cigarette Smoking Behaviors
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Sponsor	National Cancer Institute (NCI)

RESEARCH STUDY SUMMARY FOR POTENTIAL PARTICIPANTS

You are being invited to participate in a research study. Your participation is voluntary and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating 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 the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

This research study is being conducted to examine the effects of IQOS use on smoking behaviors. IQOS is a heat-not-burn (HNB) tobacco product that utilizes an electronic device to heat tobacco rather than burning it. This product contains a small, disposable tobacco stick (HeatStick) that is inserted into the device and heated to produce a tobacco-flavored vapor. The study-provided IQOS devices and HeatSticks you will receive are commercially available and approved for sale by the Food and Drug Administration (FDA). During your participation in this study, you'll be asked to attend 8 in-person sessions. Between the first two sessions of the study, you will continue to smoke your own usual brand of cigarettes. At the Day 7 visit, you will be provided with an IQOS device and HeatSticks and instructed to switch completely from smoking cigarettes to using IQOS for the remainder of the study. You are being invited to participate in this research study because you

are a current cigarette smoker and may meet other study criteria. This is not a quit smoking study.

If you agree to join the study, you will be asked to complete the following research procedures:

- Complete a urine drug screen
- Complete a breath alcohol (BrAC) assessment and carbon monoxide (CO) breath assessments
- Answer questions about your medical history (to confirm final eligibility) and smoking behaviors
- Complete computer tasks and questionnaires about your smoking behavior and other smoking related topics
- Use the IQOS device in our ventilated smoking laboratory (lab)
- Collect and return all of your used cigarette filters and HeatSticks filters in date-labeled baggies provided to you by our Center

Once your final eligibility is confirmed, your participation in this study will last about 3 weeks (approximately 21 days).

You are not expected to get any direct benefit from being in this research study. Others will be able to potentially benefit from this study by allowing us to learn more about how IQOS use affects cigarette smoking behaviors. The most common risk of participation is a shift in smoking behavior since you may smoke cigarettes in addition to using the study-provided IQOS.

The alternative to participating in this study is not to participate. If you would like to quit smoking now or at the end of this study, we can refer you to a quit smoking program at our Center or other programs in the Philadelphia area.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

WHY AM I BEING ASKED TO VOLUNTEER?

You are being invited to participate in this research study because you currently smoke cigarettes and meet other study criteria. This is not a quit smoking study. Your participation in this research study is voluntary. This means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You will still be able to participate in future studies at our Center.

Today, the research team is going to talk to you about the research study. They will tell you what the study is about, the possible risks and benefits of being in this study, and what you will have to do in order to participate. You will be given a copy of this combined Informed Consent and HIPAA authorization form to read. You may find some of the medical language difficult to understand. If you do not understand what you are reading, do not sign this form. Please ask the research staff to answer any questions you may have. You may also decide to discuss it with your family, friends, or family doctor. If you decide to participate, you will be asked to sign this form.

WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

This study will examine the effects of using the study-provided IQOS device on cigarette smoking behaviors.

HOW LONG WILL I BE IN THE STUDY?

Once your final eligibility is confirmed, your participation in this study will last about 3 weeks (i.e., approximately 21 days). This will include 8 study visits. 3 of these visits will take 1.5-2 hours and the remaining 5 will take 15-30 minutes. The overall study itself is expected to last about 1 year.

WHAT AM I BEING ASKED TO DO?

During your participation in this study, you'll be asked to attend 8 in-person sessions over a period of approximately 21 days. All study sessions will occur at

the Center for Interdisciplinary Research on Nicotine Addiction (CIRNA), also known as the Tobacco Use Research Center, every 3 to 6 days. Between the first two visits of the study, you will continue to smoke your own usual brand of cigarettes. At the end of Day 7 Visit, you will be provided with an IQOS device and HeatSticks and instructed to switch completely from smoking cigarettes to using IQOS for the remainder of the study. The study-provided IQOS devices and HeatSticks you will receive are commercially available and approved for sale by the Food and Drug Administration (FDA). Between every session, you will be asked to collect and return all of your used cigarette filters and HeatSticks in the date-labeled baggies provided to you by our Center. Specific information about each session is provided in the text below.

Intake Visit (Day 0):

During today's ~1.5 hour session, you will complete the following:

- Complete the study informed consent and HIPAA form in its entirety with the research staff. You will have the opportunity to have your questions answered before signing the study consent and HIPAA form. If you choose not to sign this form, no procedures will be performed.
- Complete a urine drug screen (at least 30ml [two tablespoons] of urine). The urine drug screen will assess the use of any study-prohibited medications and recreational drugs. These prohibited medications and recreational drugs are cocaine, opiates, amphetamines, methamphetamines, PCP, ecstasy/"molly" (MDMA), barbiturates, benzodiazepines, methadone, and/or oxycodone. For safety purposes and for the purpose of collecting reliable data, participants who test positive for the urine drug screen will be excluded from the study. Results from this testing are used for research purposes only and will not be reported to you. You will be informed of your eligibility status after the urine drug screen, but specific results will not be revealed.
- FEMALE PARTICIPANTS ONLY: Complete a urine pregnancy test. You will be provided with a urine sample cup and simple pregnancy test strip and will be instructed to perform the pregnancy test independently. For safety purposes, we ask that participants who think they may be pregnant discontinue study participation. There is no penalty for withdrawing from

the study at this point, but please note you will not be compensated for the study visit. After self-administering the urine pregnancy test, participants will be asked if they would like to proceed with their participation.

- Complete a breath alcohol concentration (BrAC) assessment. A breath alcohol reading greater than 0.000 will result in exclusion from the study.
- Complete a carbon monoxide (CO) breath assessment to verify your smoking status. CO is a poisonous gas that comprises less than 1% of the air we breathe and is also produced through smoking a cigarette. Your CO levels provide an indication of how much smoke you have been exposed to. Your CO level needs to be greater than or equal to 10 parts per million to be eligible for the study.
- Complete a medical history form with a member of the research team and provide information on medications you are currently taking or recently discontinued.
- Have your height and weight measured.
- Complete questionnaires and a Program Referral Form (electronically and/or on paper).
- You will be asked questions about your use of marijuana, other tobacco products (besides cigarettes), or if you have vaped any substance including tobacco/nicotine or other drugs in the past month.
- You will be instructed to smoke cigarettes as usual for the first five days of the study (Days 1 through 5).
- You will be instructed to engage in overnight smoking abstinence (10 hours without smoking) the night of Day 5 in preparation for the Day 6 Visit.
- Before you leave the Center today, you will schedule your next study visit. You will also receive date-stamped cigarette filter collection baggies and important take-home study instructions. As noted above, you will be responsible for supplying and smoking your <u>own brand of cigarettes</u> until your next session (the Day 6 Visit).

As you complete the tasks listed above, there is a chance you may not meet all of the study eligibility criteria (i.e., study conditions). If this occurs, you will be deemed ineligible for the study. Study eligibility conditions have been established for data

quality and/or safety purposes. You will be provided $10 compensation for successfully completing the Intake Visit today. At the end of this visit, you will be instructed to engage in overnight smoking abstinence (10 hours without smoking) on Day 5 in preparation for the Day 6 Visit, which will occur at 9:00 AM. You will be instructed to stop smoking after 11:00 PM on Day 5.

Day 6 Visit:

The Day 6 Visit will be about 2 hours long. You will arrive at the Center at 9:00 AM after having abstained from smoking overnight. At the beginning of the session, you will return the spent cigarette filters you have been collecting in the date-stamped baggies. Next, you will complete CO breath assessments, answer items concerning marijuana use, and provide information on your daily smoking rate and any medications not previously reported.

At this point, you will receive instructions on how to use the IQOS prior to two IQOS HeatStick smoking sessions (one regular, one menthol). You will be required to use the IQOS device in our smoking lab. First, you will take 14 puffs from the regular HeatStick. You will then complete a standardized 45 minute waiting period in the lab. After the waiting period, you will take 14 puffs from the menthol HeatStick. In addition, you will complete questionnaires (electronically and/or on paper) after smoking each HeatStick. You will be instructed to engage in overnight smoking abstinence (10 hours without smoking) in preparation for the Day 7 Visit, which will occur the following day at 9:00 AM. You will be instructed to stop smoking after 11:00 PM on Day 6.

Day 7 Visit:

The Day 7 visit will be about 2 hours long. You will arrive at the Center at 9:00 AM after having abstained from smoking overnight. At the beginning of the session, you will complete a CO breath assessment, answer items concerning marijuana use, and provide information on your daily smoking rate and any medications not previously reported. You will complete questionnaires and a randomized computer task where you will earn puffs toward either the IQOS device or one of your own cigarettes. After you redeem these puffs, there will be a standardized 1-hour wait

period. You will then be required to use the IQOS for the remainder of the study. At this visit, you will receive an IQOS device, your first 7-day supply of regular and/or menthol HeatSticks, and 14 date-stamped zipped baggies to collect spent cigarette filters and HeatSticks (7 for cigarettes, 7 for HeatSticks). A member of the research staff will review instructions for IQOS use and the collection and storage of used HeatSticks with you.

After the standardized 1-hour wait period, you will be instructed to switch completely from smoking cigarettes to using IQOS for the remainder of the study.

Day 11 Visit:

The Day 11 visit will be about 30 minutes long. At the beginning of the session, you will return the used HeatSticks and cigarette filters (if applicable) you have been collecting in the date-stamped baggies. Next, you will complete a CO breath assessment and questionnaires, answer items concerning marijuana use, and provide information on your daily smoking rate and any medications not previously reported.

Day 14 Visit:

The Day 14 visit will be about 30 minutes long. At the beginning of the session, you will return the used HeatSticks and cigarette filters (if applicable) you have been collecting in the date-stamped baggies. Next, you will complete a CO breath assessment and questionnaires, answer items concerning marijuana use, and provide information on your daily smoking rate and any medications not previously reported. You will received your second 7-day supply of regular and/or menthol HeatSticks, and 14 date-stamped zipped baggies to collect spent cigarette filters and HeatSticks (7 for cigarettes, 7 for HeatSticks).

Day 17 & Day 21 Visits:

The Day 17 and Day 21 Visits will be about 30 minutes long. At the beginning of the session, you will return the used HeatSticks and cigarette filters (if applicable) you have been collecting in the date-stamped baggies. Next, you will complete a CO breath assessment and questionnaires, answer items concerning marijuana

use, and provide information on your daily smoking rate and any medications not previously reported.

Day 22 Visit:

The Day 22 Visit will be about 30 minutes long. You will return the used HeatSticks and cigarette filters (if applicable) you have been collecting in the date-stamped baggies. A member of the research staff will review important information about the risks of smoking and provide referrals for a smoking cessation program at our Center or in the Philadelphia area if you are interested.

Throughout your entire participation in this study, we ask that you:

- Not use any other forms of nicotine (e.g., nicotine gum, nicotine patch, lozenge, e-cigarette, JUUL, other vape device, etc.) except for your own preferred brand of cigarettes or IQOS between Day 7 and Day 21 of the study.
- Bring all of your unused study-provided HeatSticks in their original package and used cigarette filters and HeatSticks in the appropriate date-stamped baggies to each session.
- Not participate in any other quit smoking programs and/or quit smoking research studies while you are enrolled in this study.
- FEMALES ONLY: Notify us immediately if you become pregnant. You may not participate if you are pregnant or nursing. You should use a medically accepted method of birth control (such as IUD, birth control pills, condoms, etc.) while participating in this study.
- Attend all study sessions as scheduled and notify the research staff if you're ever running late or need to reschedule as far in advance as possible.

Please note that failure to follow these study instructions may lead to exclusion from the study.

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS?

The likelihood and severity of the possible risks to you are described below. Overall, there is minimal risk for serious adverse reactions as a consequence of enrolling in this research study.

Assessments: Some participants may experience some emotional distress during study assessments due to learning their CO levels, and seeing how many cigarettes and/or HeatSticks they smoke. These events happen very rarely and in almost all cases are short-lived and of low intensity. If you happen to exhibit high levels of emotional distress, however, you will be provided with contact information for mental health services in the area.

Cigarette Smoking and IQOS Use: Cigarette smoking has been shown to cause diseases such as emphysema and cancer. Since you are a current smoker, we do not believe the risk of continuing to smoke during the study is beyond the everyday risk of smoking cigarettes. The study-provided IQOS device you will be asked to use is commercially available and approved for sale by the Food and Drug Administration (FDA). There will be a phase of the study where you will be instructed to switch completely to IQOS. If you don't completely switch from smoking cigarettes to using IQOS, your risks from smoking will remain the same.

Important safety information regarding IQOS: **IQOS works exclusively with HeatSticks.** Never use IQOS with a cigarette or any other tobacco sticks or accessories. Do not remove a tobacco stick (HeatStick) while in use. Tobacco sticks (HeatSticks) are single use only and should never be reused. Tobacco sticks (HeatSticks) should never be lit with a match, lighter, or any other flame source. **Keep tobacco sticks out of reach of children and pets.** If tobacco sticks are swallowed, seek medical attention immediately due to risk of nicotine ingestion. **Store your tobacco sticks in a cool, dry place.** Do not expose product to high humidity conditions or direct sunlight. Do not use IQOS during hot conditions or in periods of high humidity. **Pay attention to signs that your battery may be leaking.** The IQOS Holder and Pocket Charger are powered with sealed Lithium-ion batteries. Under normal conditions of use, the battery is sealed. If you notice fluid leaking from the battery, follow these precautions, discontinue using the product immediately and contact Divya Manikandan at 215-746-3782. In case of contact with skin, wash hands and do not touch eyes. In case of contact with eyes, immediately flush with running water for at least 15 minutes and seek medical attention. If fluid is inhaled, get fresh air and seek medical attention. If you swallow fluid, seek medical attention immediately. Do not induce vomiting or ingest food or drink. **Stop using IQOS and seek medical**

attention immediately if you experience any symptoms that may indicate a serious allergic reaction: swelling of the face, lips, tongue, gums, throat, or body; difficulty breathing, or wheezing.

Potential Loss of Confidentiality: Every attempt will be made by the Principal Investigator to keep all information collected in this study strictly confidential. We will store your information in a secure room with limited access. We will control access to the computer files that hold your information. Only people working on this research project identified in this combined Informed Consent and HIPAA Form can work with your information. When the results of the study are published, no names or identifying information will be used.

Email Communications: Throughout this research study you may receive appointment reminders via email or elect to submit questions related to the logistics of the study via email. Email is not a secure means of communication. Email messages travel across the Internet passing through multiple computers before reaching their final destination. It is not possible to know whether an email you send will be viewed along the way. Additionally, if sent messages are not deleted, an email provider may have an archive of everything that is sent. If someone gets access to an email account (for example, a family member), they could see archived messages. There are many other ways in which emails are not secure - these are only selected examples. For these reasons we ask that you only use email communication for routine matters and never for personal or confidential messages or questions. If you have questions or concerns that are personal in nature, we urge you to contact the study team via phone.

Reproductive Risks: Smoking can cause serious harm to unborn children or children who are breast-feeding. If you are currently pregnant and/or breast-feeding, it is important that you inform the Principal Investigator. You will not be able participate in this study if you are pregnant, become pregnant, or are breast-feeding. You are asked to use a medically accepted method of birth control (such as IUD, birth control, or condoms) while you participate in this study. If you become pregnant during the study, you should notify the research staff immediately and you will be withdrawn. You will also be instructed to consult an

obstetrician or maternal-fetal specialist about the dangers of smoking while pregnant.

Withdrawal Symptoms: You may experience uncomfortable withdrawal symptoms during your overnight smoking abstinence. In preparation for overnight smoking abstinence, you will receive tips from study staff for remaining abstinent (e.g., coping with withdrawal and craving, smoking triggers, coping with stress). These symptoms will be short-lived, and you will be able to self-administer nicotine in the laboratory the following morning.

Other Risks: This research may involve risks that are currently unforeseeable. If you believe you have experienced a notable symptom or medical event/issue as a result of this research study, please inform the research staff with your concerns.

WHAT IF NEW INFORMATION BECOMES AVAILABLE ABOUT THE STUDY?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

WHAT ARE THE POSSIBLE BENEFITS OF THE STUDY?

You are not expected to get any direct benefit from being in this research study. Others will be able to potentially benefit from this study by allowing us to learn more about how IQOS use affects cigarette smoking behaviors. If you would like to quit smoking at the end of this study, we can refer you to a quit smoking research program at our Center or other non-research quit smoking programs in the Philadelphia area.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT PARTICIPATE?

The alternative to participation is to decide not to enroll in the study. Your participation is voluntary.

WILL I BE PAID FOR BEING IN THIS STUDY?

Because we appreciate you donating your time to contribute to this research, you will have the opportunity to receive up to $500.00 for completing all of the study requirements. You will be compensated per the study payment table below. The "task completion" compensation will depend on you arriving on time for scheduled sessions, collecting used cigarette filters and HeatSticks, tracking the number of cigarettes and HeatSticks you smoke daily, and unused HeatSticks in their original packaging (when applicable). If you do not follow the study instructions, some or all of the task completion compensation may be withheld and you may be withdrawn from the study.

You will be asked to complete a W-9 tax form (includes social security number) at the conclusion of today's session because the University of Pennsylvania is required to report to the Internal Revenue Service (IRS) any total payments for participation in research studies at the University of Pennsylvania that exceed a total of $600.00 in a calendar year. A W-9 will aid the Center and University in tracking and reporting those who participate in multiple projects and may accrue over $600.00 in a calendar year. Further, a social security number is required to register each participant for a Greenphire ClinCard (described below).

If you are eligible for the study after successfully completing the Intake Visit, you will be given a Greenphire ClinCard, which is a reloadable, pre-paid card for the purposes of compensation. Compensation will be loaded onto the ClinCard at the end of each completed session as appropriate. You will be given the option to receive a text message alert when a payment has been loaded to the ClinCard.

Study Payment				
Visit	**Visit Compensation**	**Travel Reimbursement**	**Task Completion**	**Total**
Intake	$10.00	N/A	N/A	$10.00
Day 6 Visit	$35.00	$5.00	$35.00	$75.00
Day 7 Visit	$40.00	$5.00	N/A	$45.00
Day 11 Visit	$20.00	$5.00	$45.00	$70.00
Day 14 Visit	$20.00	$5.00	$45.00	$70.00
Day 17 Visit	$20.00	$5.00	$45.00	$70.00
Day 21 Visit	$20.00	$5.00	$60.00	$85.00
Day 22 Visit	$55.00 Bonus	$5.00	$15.00	$75.00
			Study Total	$500.00

WILL I HAVE TO PAY FOR ANYTHING?

You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study. Study-provided IQOS and HeatSticks will be distributed to you at no cost during the Day 7 and Day 14 Visits.

WILL I RECEIVE THE RESULTS OF RESEARCH TESTING?

Most tests done in research studies are only for research and have no clear meaning for health care. Research results will not be returned to you because they would not be relevant to your health care. Specific research results from this study will not be placed in your medical record.

WHAT HAPPENS IF I AM INJURED FROM BEING IN THE STUDY?

If you think you have been injured as a result of taking part in this research study, please contact the Principal Investigator, Janet Audrain-McGovern, Ph.D., at 215-746-7145. We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal

right to seek payment, even though you are in a study. You do not give up your legal rights by signing this form.

WHEN IS THE STUDY OVER? CAN I LEAVE THE STUDY BEFORE IT ENDS?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your physician, the study funding Sponsor, or the Food and Drug Administration without your consent because:

- The Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions or present with something that is considered to be exclusionary for this study.
- The study funding Sponsor, the Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care.

Could I be withdrawn from the study?

You have the right to drop out of the research study at any time during your participation. There is no penalty or loss of benefits to which you are otherwise entitled if you do so. If you no longer wish to be in the research study, please contact Principal Investigator Janet Audrain-McGovern at 215- 746-7145.

You could be removed from the study if you are persistently absent from scheduled visit, consistently fail to correspond with study staff, pose a threat to the safety of others in the center, are disruptive or non-compliant with the research process, or if the research team deems your data as unreliable. If you are withdrawn from the study during the study period, you will be notified via your

preferred method of communication and will receive all compensation and benefits you were entitled to up until the period of your involvement in the study, but no further. If your data are withdrawn after your study participation is complete, you may not be contacted with information regarding the withdrawal, however, you will receive all the compensation and benefits you were entitled to up until the period of your involvement in the study.

HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Food and Drug Administration, the National Cancer Institute, and the University of Pennsylvania's Office of Clinical Research and Institutional Review Boards may review your research records.

All data collection forms in this study will be labeled with your study ID (not your name). All electronic data will be secured and stored in accordance with University of Pennsylvania guidelines and HIPAA standards with the goal of protecting your privacy. All data that can be linked to your study ID will be stored in a secure data management system with password-required access or a locked cabinet.

WHAT MAY HAPPEN TO MY INFORMATION COLLECTED IN THIS STUDY?

Future Use of Data

We would like to retain the information you provide, such as demographic information, smoking behavior, and questionnaire responses, for possible use in future research. You will likely not directly benefit from future research with your information, but the information you provide could be useful for future researchers who want to learn more about IQOS use. There are no plans to tell you specific details about any of the future research that will be done. Further, we will not give

you any results from these future studies. It is possible that you may have chosen not to participate in these future research studies had you been approached for participation.

Your information collected in this study will be labeled and stored with a study identification number only (not your name or other direct personal identifiers). However, there is a possibility that your study identification number and your personal identifiers could be linked. Therefore, there is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure this does not happen. Other sections of this Informed Consent and HIPAA Form provide additional information on how we will protect your information and keep it confidential.

Permission to retain your information for use in future research is optional and you will be asked to indicate your choice at the end of this form. You may change your mind and withdraw your permission for the future use of your information at any time by contacting the Principal Investigator, Janet Audrain-McGovern, Ph.D., at 215-746-7145 and letting them know that you no longer want your information to be maintained for use in future research.

Your identifiable information will be maintained for future research purposes only. Your information may be maintained and used for future research for an indefinite amount of time. Future researchers may receive information that could identify you. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected in this study.

ELECTRONIC MEDICAL RECORDS AND RESEARCH RESULTS

What is an Electronic Medical Record and a Clinical Trial Management System?:

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.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research. You will be registered in the CTMS, but information from your participation in this study will not be entered in your EMR. Research staff will not be accessing your EMR if you have one at the University of Pennsylvania Health System (UPHS).

Information related to your participation in clinical research will be contained in the CTMS. Once placed in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. For this study, we will only enter some basic demographic data and your study status into the PennCTMS. We will not enter any specific research results.

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

- Name, address, telephone number, and email address
- Date of birth
- Demographic information, such as years of education, household income, etc.
- Personal medical history
- Social security number (documented on the W-9 form)
- Results from all questionnaires, tests, or procedures

WHY IS MY INFORMATION BEING USED?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- Do the research
- Oversee the research
- To see if the research was done right
- To evaluate and manage research functions

WHO MAY USE AND SHARE INFORMATION ABOUT ME?

The following individuals may use or share your information for this research study:

- The Principal Investigator, Co-Investigators, the Investigators' research team, and authorized members of the Center for Interdisciplinary Research on Nicotine Addiction (CIRNA)
- 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 which monitors research studies)
- Other authorized personnel at the University of Pennsylvania who may need to access your information in the course of their duties (i.e., research oversight, compensation processing, etc.)
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the University of Pennsylvania Institutional Review Boards

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

Your information will only be shared with the following institutions that are involved in the protection and safety of human research subjects:

- The Food and Drug Administration
- The National Cancer Institute
- The Office of Human Research Protections (provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research)

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

HOW LONG MAY THE SCHOOL OF MEDICINE USE OR DISCLOSE MY PERSONAL HEALTH INFORMATION?

Your authorization for use of your personal health information for this specific study does not expire. Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

CAN I CHANGE MY MIND ABOUT GIVING PERMISSION FOR USE OF MY INFORMATION?

Yes. 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 the Principal Investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

WHAT IF I DECIDE NOT TO GIVE PERMISSION TO USE AND GIVE OUT MY HEALTH INFORMATION?

You will not be able to be in this research study.

You will be given a copy of this combined Informed Consent and HIPAA Authorization Form describing your confidentiality and privacy rights for this study. By signing this document you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

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 study 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 team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs at the University of Pennsylvania with any questions, concerns or complaints by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. 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 to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

Name of Participant (Please Print)	Signature of Participant	Date

Name of Person Obtaining Consent (Please Print)	Signature	Date

Use of your Information for Future Research:

Please check **YES** and record your initials if you give permission for us to retain your information and store your urine samples from this study for use in future research. Please check **NO** and record your initials if you do not give us permission to retain your information and store your urine samples from this study for use in future research.

☐ **YES** ☐ **NO** Participant Initials: _____