Institutional Review Board
3600 Civic Center Blvd., 9th Floor
Philadelphia, PA 19104
Phone: 215-573-2540
(Federalwide Assurance # 00004028)

DATE: 27-Sep-2022
TO: Janet E Audrain-Mcgovern
CC:

RE:
IRB PROTOCOL#: 843944
PROTOCOL TITLE: The effect of sweet flavoring on the rewarding and reinforcing value of cigarillo use among young adults

SPONSOR: NO SPONSOR NUMBER
REVIEW BOARD: IRB #8

IRB AMENDMENT: NOTICE OF APPROVAL

Dear Dr. Audrain-Mcgovern,

The documents noted below, for the above-referenced protocol, were reviewed by the Institutional Review Board using the expedited procedure set forth in 45 CFR 46.110 and approved on 26-Sep-2022.

This study has been determined to pose minimal risk to subjects. IRB approval for the study will expire on 09-Jun-2023.

The documents included with the application noted below are approved:
-HSERA Application, confirmation code: dhbacgad, submitted on 9/15/22
ONGOING REQUIREMENTS:

- You must obtain IRB review and approval under 45 CFR 46 if you make any changes to the protocol, consent form, or any other study documents subject to IRB review requirements. Implementation of any changes cannot occur until IRB approval has been given.
- Reportable event, such as serious adverse events, deviations, potential unanticipated problems, and reports of non-compliance must be reported to the IRB in accordance with Penn IRB SOP RR 404.
- When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

COMMITTEE APPROVALS: You are responsible for assuring and maintaining other relevant committee approvals. This human subjects research protocol should not commence until all relevant committee approvals have been obtained.

If your study is funded by an external agency, please retain this letter as documentation of the IRB's determination regarding your proposal.

If you have any questions about the information in this letter, please contact the IRB administrative staff. A full listing of staff members and contact information can be found on our website: http://www.irb.upenn.edu

***This letter constitutes official University of Pennsylvania IRB correspondence. ***

UNIVERSITY OF PENNSYLVANIA
COMBINED SUBJECT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	The Effect of Flavoring on the Rewarding and Reinforcing Value of Cigarillo Use among Young Adults
Principal Investigator/Emergency Contact:	Janet Audrain-McGovern, Ph.D. 3535 Market St., Suite 4100 Philadelphia, PA 19104 Phone: 215-746-7145
Sponsor	National Institute on Drug Abuse (NIDA)

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 flavored cigarillo use among young adults. During your participation in this study, you'll be asked to attend 3 in-person sessions and smoke study-provided cigarillos. The study-provided cigarillos you will receive are commercially available and authorized for sale by the Food and Drug Administration (FDA). You are being invited to participate in this research study because you have smoked 10 or more cigarillos in your lifetime and may meet other study criteria. This is not a tobacco cessation 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 carbon monoxide (CO) and breath alcohol (BrAC) assessments
- Answer questions about your medical history (to confirm final eligibility) and smoking behaviors
- Complete questionnaires about your smoking behaviors, marijuana use, and other smoking related topics
- Smoke study-provided cigarillos in our ventilated smoking laboratory (lab) while being recorded on video so we can measure how you smoke

Once your final eligibility is confirmed, your participation in this study will last 2 to 3 weeks.

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 cigarillo flavoring affects cigarillo-smoking behaviors.

The alternative to participating in this study is not to participate. If you would like to quit smoking tobacco now or at the end of this study, we can refer you to a tobacco cessation 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 are a young adult, have used 10 or more cigarillos in your lifetime, and meet other study criteria. This is <u>not</u> a tobacco cessation 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 flavored cigarillo use among young adults.

HOW LONG WILL I BE IN THE STUDY?

Once your final eligibility is confirmed, your participation in this study will last 2 to 3 weeks. This will include 3 study visits that will take 1.5-2.5 hours each. The overall study itself is expected to last about 18 months.

WHAT AM I BEING ASKED TO DO?

During your participation in this study, you'll be asked to attend 3 in-person sessions over a period of 2 to 3 weeks. All study sessions will occur at the Center for Interdisciplinary Research on Nicotine Addiction (CIRNA), also known as the Tobacco Use Research Center. You will smoke study-provided cigarillos in our ventilated smoking laboratory at 3 separate laboratory visits. Specific information about each session is provided in the text below.

Visit 1:

During today's ~2 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 and you will still receive travel reimbursement. After self-administering the urine pregnancy test, participants will be asked if they would like to proceed with their participation.
- Your urine sample may be used to conduct a urine cotinine assessment. Cotinine is a by-product of nicotine metabolism, or nicotine breakdown. The presence of cotinine in your urine sample will be used to measure your exposure to products that contain nicotine.
- 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. Your CO levels provide an indication of how much smoke you have been exposed to.
- Complete a medical history form with a member of the research team and provide information on medications you are currently taking or recently discontinued.
- Complete questionnaires (electronically and/or on paper).
- You will be asked questions about your use of marijuana, other tobacco products, or if you have vaped any substance including tobacco/nicotine or other drugs in the past month.

- If you are a regular tobacco user, you will be instructed to use tobacco as usual prior to Visit 1.
- Before you leave the Center today, you will schedule your next study visit with a member of the research team.

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. If you successfully complete all of these tasks, you will receive $55 for your time, which includes $5 for transportation compensation. If you are deemed ineligible at any point during this visit, we will only compensate you $5 to cover your travel costs.

If you are eligible to participate and decide to enroll in the study, you will complete the following additional tasks:

- Be required to use study-provided cigarillos during a session in our ventilated smoking lab. During this smoking task, you will sample two puffs from each of three cigarillos. The sampling of each cigarillo will be separated by a 20 minute standardized waiting period.
- Schedule your next study visit.
- Remain tobacco abstinent (e.g., not using combustible cigarettes, e-cigarettes, cigars, blunts) for 10 hours in preparation for Visit 2, which will occur at approximately 1:00 PM on the scheduled date. You will be instructed to stop smoking 10 hours before Visit 2 is scheduled to begin.

Visit 2:

Visit 2 will be about 2 hours long. You will arrive at the Center at approximately 1:00 PM after having abstained from tobacco (e.g., combustible cigarettes, e-cigarettes, cigars, blunts) for 10 hours. 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 may be asked to provide a urine sample for cotinine analysis. You will complete questionnaires and a randomized computer task where you will earn

puffs toward a cigarillo flavor of your choosing. You will then be required to take earned cigarillo puffs in our smoking laboratory, and complete a standardized 1-hour wait period. A member of the research staff will schedule Visit 3. You will be instructed to remain tobacco abstinent (e.g. combustible cigarettes, e-cigarettes, cigars, blunts) for 10 hours in preparation for Visit 3, which will occur at 1:00 PM on the scheduled date.

Visit 3:

Visit 3 will be about 2.5 hours long. You will arrive at the Center at approximately 1:00 PM after having abstained from tobacco (e.g. combustible cigarettes, e-cigarettes, cigars, blunts) for 10 hours. At the beginning of the session, you will complete a CO breath assessment to make sure that you have not smoked in 10 hours, answer items concerning marijuana use, and provide information on your daily smoking rate and any medications not previously reported. You may be asked to provide a urine sample for cotinine analysis to make sure that you have not used e-cigarettes in 10 hours.

Next, you will be required to use study-provided cigarillos during a session in our smoking lab, where you will smoke one of the three flavored cigarillos you sampled at Visit 1 in our ventilated smoking lab for 90 minutes. You will be recorded on video so we can collect data about how you smoke. You will be able to smoke a cigarillo while in the lab while you periodically complete questionnaires during this 90-minute laboratory waiting period. The laboratory session will be followed by a 30-minute period of enforced abstinence from tobacco use.

A member of the research staff will review important information about the risks of smoking cigarillos and provide referrals for a tobacco 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 forms of nicotine replacement therapy (e.g., nicotine gum, nicotine patch, nicotine lozenge) or smoking cessation medication.
- Not participate in any other tobacco research studies or cigarette smoking cessation programs 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.

Cigarillo Smoking: The study-provided cigarillos you will be asked to smoke are commercially available. During the course of this study, you will smoke flavored and/or unflavored cigarillos. At Visit 1, you will take 6 puffs of a cigarillo. At Visit 2, you will take 10 puffs of a cigarillo. At Visit 3, the number of puffs you take is up to you. Some participants may experience certain symptoms while taking puffs of tobacco products including cigarillos, such as nausea, dizziness, and/or rapid heartbeat. These feelings are typically mild and relatively short-lived. These symptoms are more common among individuals who have not had prior exposure to tobacco products and thus have not had previous exposure to nicotine. The chances that you will experience these symptoms are less likely because you have had prior nicotine exposure. If you do experience these symptoms, let a member of the research staff know immediately and you will be permitted to extinguish your cigarillo.

Withdrawal Symptoms: If you regularly use combustible cigarettes and/or e-cigarettes, you may experience uncomfortable withdrawal symptoms during your 10-hour tobacco product abstinence period. In preparation for 10-hour tobacco abstinence, you will receive tips from study staff for remaining abstinent (e.g., coping with withdrawal and craving, triggers, coping with stress). These symptoms will be short-lived, and you will be able to self-administer nicotine in the laboratory the following day.

Assessments: Some participants may experience some emotional distress during study assessments due to learning their CO levels. 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.

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.

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. Other young adults may potentially benefit from this study by allowing us to learn more about cigarillo smoking behaviors. At the end of this study, if you would like to quit using tobacco, we can refer you to programs at our Center or other non-research 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 $240.00 for completing all of the study requirements. You will be compensated per the study payment table below. 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 Visit 1, 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.

Visit	Visit Compensation	Travel Reimbursement	Total
Visit 1	$50.00	$5.00	$55.00
Visit 2	$60.00	$5.00	$65.00
Visit 3	$75.00	$5.00	$80.00
BONUS	$40.00 BONUS	N/A	$40.00
		TOTAL:	$240.00

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 cigarillos will be distributed to you at no cost during sessions in our smoking lab at Visits 1, 2, and 3.

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 cigarillo 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?

- The following information will be collected: 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

A description of this clinical trial will be available on http://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.

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 Institute on Drug Abuse
- 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.

FLAV

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: _____