UNIVERSITY OF PENNSYLVANIA
COMBINED SUBJECT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	Cigar Packaging Study
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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 smoking cigarillos supplied to you by the research team. The study-provided cigarillos you may receive are commercially available and similar to the cigarillos you currently smoke. During your participation in this study, you'll be asked to attend 6 sessions. Between the first two sessions of the study, you will continue to smoke your own usual brand of cigarillos. At Session 2, you will be assigned to smoke cigarillos supplied to you by our staff for the remainder of the study. You are being invited to participate in this research study because you are a current cigarillo 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:

- Answer questions about your medical history (to confirm final eligibility) and smoking behaviors
- Complete questionnaires about your smoking behavior and other smoking related topics
- Smoke cigarillos in our ventilated smoking laboratory (lab) and at home while being recorded on video so we can measure how you smoke

IRB Approval From: 09-30-2021

- Provide two small urine samples
- Collect and return all of your used cigarillo “tips/ends” 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 20 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 having improved tobacco policy put into effect that will reduce the impact of cigarillo smoking on the population of the United States. The most common risk of participation is a shift in smoking behavior since you may smoke more cigarillos each day and may change how intensely you smoke each cigarillo.

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 cigarillos 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. 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 smoking cigarillos supplied to you by the research team.

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 20 days). The study itself is expected to last a period of 1-2 years.

WHAT AM I BEING ASKED TO DO?

During your participation in this study, you'll be asked to attend 6 sessions over a period of approximately 20 days. Study sessions will occur at the Center for Interdisciplinary Research on Nicotine Addiction (CIRNA), also known as the Tobacco Use Research Center, and remotely (i.e. by phone or video call) every 3-5 days. Between the first two sessions of the study, you will continue to smoke your own usual brand of cigarillos. At Session 2, you will be assigned to smoke study-provided cigarillos. The study-provided cigarillos you'll receive are commercially available cigarillos that are similar to the cigarillos you currently smoke. After Session 2, you must only smoke the study-provided cigarillos for the remainder of the study. At Session 2, you will be asked to collect and return all of your used cigarillo tips/ends in the date-labeled baggies provided to you by our Center for the remainder of the study.

Specific information about each session is provided in the text below.

Session 1 (Day 0):

During today's ~1 hour session, you will complete the following:

1. Confirm the accuracy of information you provided during the initial Telephone Eligibility Screen, which includes your preferred cigarillo and cigarette brand (if you smoke cigarettes).
    - You must have a pack of your own brand of cigarillos with you today to continue with the study. If you do not have your pack of cigarillos, we may need to reschedule your Session 1 to a later date or you may be deemed ineligible to participate. You will not receive any compensation for attending the session today if you do not present a pack of your preferred brand of cigarillos.

2. Review the combined Informed Consent and HIPAA Form. All of your questions about the study will be answered. Following this presentation, if you would like to participate in the study, you will be asked to electronically sign and date this combined Informed Consent and HIPAA Form with a member of the research staff.

3. You will be asked questions about your use of marijuana, other tobacco products (besides cigarettes or cigarillos), or if you have vaped any substance including tobacco/nicotine or other drugs in the past month.

4. Complete a medical history and medication review form with the research staff.

5. Complete a Program Referral Form and questionnaires (electronically) about your demographics, smoking behavior, alcohol use, cigarillo and blunt use, and other smoking related topics.

6. Review and receive a copy of your study calendar. As noted above, you will be responsible for supplying and smoking your own brand of cigarillos until your next session (Session 2/Day 5).

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 the session procedures today, you will be compensated $40 for your time and effort at your first in person session (Session 2/Day 5). If you are deemed ineligible during today's session, you will not receive any compensation ($0).

Session 2 (Day 5):

Session 2 will be about 1.5 hours long. At the beginning of the session you will provide a urine sample (~4 tablespoons). Females will also be asked to complete a simple, one-step urine pregnancy test. If you believe you may be pregnant, you must immediately withdraw from the study. Next, you will report on both your smoking behavior since your last session and the use of other substances.

At this point, you will be randomly assigned (i.e., a process similar to flipping a coin) to smoke one of two different versions of study-provided cigarillos for the rest of the study. It is extremely important that you only smoke the cigarillos that we provide to you for the remainder of the study. You will smoke your first study-

provided cigarillo in our smoking lab while being video recorded as described above. In addition, you will complete questionnaires (electronically and/or on paper) related to the lab cigarillo and other smoking related topics. You will depart the center with enough study-provided cigarillos to smoke until your next scheduled product pick up visit on Day 9 (Session 3).

Sessions 3-6 (Day 9, 12, 16 and 20):

Sessions 3-6 will be approximately 1.5 hours each and will be very similar to the first two sessions, except sessions 3-5 (Day 9, 12 and 16) will be completed remotely (i.e. by phone or video call). During these remote sessions you will report on your smoking behavior since your last session and the use of other substances, smoke a study-provided cigarillo while being recorded on video and complete questionnaires (electronically) about smoking related topics.

At Session 3 (Day 9) you will be asked to attend a product pick up visit in addition to completing your remote session. At this visit you will return your used cigarillo tips/ends in date-stamped baggies, empty packaging, and all unused cigarillos in their original packaging (if applicable). You will be provided with enough cigarillos to smoke between sessions until the last session on Day 20.

For Session 6 (Day 20), you will be asked to provide another urine sample (~4 tablespoons) at the beginning of the session. Both of the urine samples you will provide during the study will be examined for metabolites (i.e., break down products) of nicotine and tobacco. Session 6 (Day 20) will be completed in-person at our center. You will smoke a study-provided cigarillo in our smoking lab while being video recorded as described above. In addition, you will complete questionnaires (electronically and/or on paper) related to the lab cigarillo and other smoking related topics.

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 cigarillos between Session 1 (Day 0) and Session 2 (Day 5) and then only the cigarillos provided to you by our Center for the remainder of the study.

- Bring all of your unused study-provided cigarillos in their original packages, empty packages, and used cigarillo tips/ends 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 observing how many cigarillos 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.

Cigarillo Smoking: Cigarillo smoking has been shown to cause diseases such as emphysema and cancer. The study-provided cigarillos you will be asked to smoke are commercially available and are similar to the cigarillos you report smoking. During the course of this study, you may smoke more cigarillos each day. You may also change how intensely you smoke each cigarillo. Therefore, you may or may not increase your exposure to nicotine and other cigarillo smoke chemicals during the study.

Potential Loss of Confidentiality: Every attempt will be made by the Principal Investigator to keep all information collected in this study 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. Videos, that may include your face, will be stored on password-protected computers accessible to only study staff. No identifiers such as your name will be used during video recording. The risk of

breach of privacy is small and all video files will be deleted approximately four years after the study is completed or the data is no longer considered necessary. 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. You must also agree to use email to receive unique, study specific survey links and meeting links during remote sessions. 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.

Remote Visits: You will be asked to complete remote sessions for this research study using BlueJeans. BlueJeans is a HIPAA-compliant platform used by Penn Medicine for video conferencing purposes. It can be started and joined via a PC, Mac, smartphone, or regular landline (audio only). Each meeting supports recording of the meeting and screen/media sharing. This study will utilize the BlueJeans platform to complete remote sessions on Days 0, 9, 12, and 16 (Sessions 1, 3, 4 and 5). Remote sessions will occur between you and a trained research staff member who will initiate the meeting. You will be provided instructions detailing how to use the platform with your computer or other compatible device. You will be provided a unique meeting link via email. We ask that you complete all remote sessions and electronic questionnaires in a private place.

During remote sessions you will be asked to record a video of your cigarillo smoking so we can measure how you smoke. Using Penn+Box, an institutionally-approved secure share platform, we will ask you to send your videos to the lab at each remote session. A unique, file request link will be shared with you via email, so that you may upload your video files to Penn+Box. Anyone who has access to

this link may upload files to your study folder within Penn+Box. Because of this, we ask that you not share this link with anyone, as it should only be used by you for the purposes of uploading your smoking videos for the research study. As mentioned in the above section titled “Email Communications” you should understand the risks of using email. In order to participate in this research study, you must agree to use email for study purposes, including communication with research staff for routine matters and to receive unique study specific links (including REDCap questionnaire completion, BlueJeans meeting invitation links and Penn+Box file uploading invitation links).

Videos will be will be transferred by research staff from the Penn+Box platform to the research lab’s secured & managed network drive and stored on password-protected computers accessible to only study staff. When your research participation ends, your unique folder will be deleted from Penn+Box. Once the folder is deleted, you will no longer have the ability to upload any content to Penn+Box, as the link provided will no longer function. We ask that you record videos of your cigarillo smoking in a private place without audio to protect your privacy. Only people working on this research project identified in this combined Informed Consent and HIPAA Form can work with your information.

Questionnaire data will be obtained for remote sessions via REDCap. REDCap (Research Electronic Data Capture) is the primary software platform for collecting and storing questionnaire data. REDCap is a web-based application developed by Vanderbilt University to capture data for clinical research. It is HIPAA-compliant, and highly secure. You will be provided a unique survey link via email to complete remote session questionnaires.

COVID-19: By attending in-person sessions, you may put yourself at increased risk for exposure to the COVID-19 virus. Additionally, if you are using public transportation to get to your appointment, you may put yourself at increased risk for exposure to the COVID-19 virus. We advise you to wear a mask and practice social distancing while using public transportation. Please ensure that you have carefully reviewed the COVID-19 Informational Sheet before agreeing to take part in this research study. Our research center will follow guidelines to ensure minimal contact between participants and staff to mitigate exposure to the COVID-19 virus.

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. If you are injured, you should inform your treating physician that you are participating in a research study.

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 having improved tobacco policy put into effect that will reduce the impact of cigarillo smoking on the population of the United States. 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 $200.00 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, smoking the correct type of cigarillos between sessions, collecting used cigarillo tips/ends, tracking the number of cigarillos you smoke daily, and returning empty cigarillo packaging and unused cigarillos 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 Session 2 (Day 5) 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, at Session 2 (Day 5) 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. Please note, Clincard payment upload times may vary.

You will be compensated for Session 1 (D0) and Session 2 (D5) at the conclusion of Session 2 (D5), as Session 1 (D0) is completed remotely (prior to Clincard distribution). <u>If you are deemed ineligible at Session 1 (D0), you will not receive any compensation ($0).</u> At Session 3 (D9) you will receive travel reimbursement ($5) for attending a product pick up visit in addition to completing the session remotely.

Study Payment				
Session (Day)	**Visit Compensation**	**Travel Reimbursement**	**Task Completion**	**Total**
1 (0)	$30.00		$10.00	$40.00
2 (5)	$20.00	$5.00	$5.00	$30.00
3 (9)	$20.00	$5.00	$5.00	$30.00
4 (12)	$20.00		$10.00	$30.00
5 (16)	$20.00		$10.00	$30.00
6 (20)	$25.00	$5.00	$10.00	$40.00
			Study Total	$200.00

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 between Sessions 2 and 6 (Days 5 and 20).

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

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.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent 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 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. If you decide to withdraw from the study, we ask that you return any study product that was distributed to you.

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 biological samples (urine), video files, and 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.

WILL INFORMATION ABOUT THIS STUDY BE AVAILABLE TO THE PUBLIC?

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you.

WHAT MAY HAPPEN TO MY INFORMATION AND SAMPLES COLLECTED IN THIS STUDY?

Collection of Identifiable Specimens:

It is possible that your urine 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. Note that most uses of biospecimens or information do not lead to commercial products or to profit for anyone. Whole genome sequencing - analyzing your entire personal genetic code - will not be conducted on your urine samples.

Future Use of Data and Specimens:

We would like to store your urine samples and 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 and urine samples, but the information and urine samples that you provide could be useful to future researchers who want to learn more about cigarillo smoking. There are no plans to tell you about any of the specific 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.

Your information and urine samples 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 and store your urine samples 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 and urine samples at any time by contacting the Principal Investigator (contact information listed on page 1) and letting them know you no longer want your information and urine samples to be maintained for use in future research.

Your information and urine samples 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 and samples only applies to the information and urine samples collected during this study.

WILL I RECEIVE THE RESULTS OF RESEARCH TESTING THAT MAY BE RELEVANT TO MY HEALTH?

Many of tests done in research studies are only for research and have no clear impact on your healthcare. Research results for this study will not be returned to you because they would not be relevant to your healthcare.

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 IRB at the number on page one of this form.

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

- Name, address, date of birth
- Telephone numbers
- Electronic mail (Email) addresses
- Personal medical history
- Social security number
- Results from all questionnaires, tests, and procedures
- Full face images from video recordings

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

WHERE MAY MY INFORMATION BE STORED?

Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases.

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 Penn Medicine and 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 PENN MEDICINE, MIGHT RECEIVE MY INFORMATION?

- Those working under the direction of the Principal Investigator for the study (e.g., Co-Investigators at other academic institutions)
- Your urine samples may be sent to the University of Minnesota Masonic Cancer Center for analysis
- 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 Penn 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 Penn Medicine procedures developed to protect your privacy.

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

Your authorization for use of your personal health information for this specific study does not expire. However, Penn 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 Penn Medicine to use and disclose personal health information collected about you for research purposes as described above.

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 and Urine Samples 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: _____