UNIVERSITY OF PENNSYLVANIA COMBINED RESEARCH SUBJECT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	Behavioral Activation for Smoking Cessation and the Prevention of Post-Cessation Weight Gain NCT02906787
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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 better understand why people gain weight when they quit smoking and whether certain types of smoking cessation (i.e. quit smoking) counseling combined with the nicotine patch can help people quit smoking and gain less weight. In addition to the main study described above, participants who are eligible for the main study and meet certain medication-related study conditions may also elect to participate in an optional sub-study during which you will be asked to provide three self-collected stool samples. If you agree to participate in the main study, you will be asked to complete the following procedures:

- Attend up to 11 in-person visits that include 8 smoking cessation counseling sessions, questionnaires, and computer tasks
- Wear a nicotine patch for 8 weeks

- Complete three 24-hour dietary recall assessments over the telephone or in person at 5 separate time points (a total of 15 assessments) to measure what you ate and drank the day before
- Complete a urine drug screen
- Complete a breath alcohol (BrAC) assessment and carbon monoxide (CO) breath assessments or potentially provide urine samples for cotinine assessment
- Potentially provide two small saliva samples
- Provide 3 self-collected stool samples (optional sub-study only)

Once your final eligibility is confirmed, your participation in this study will last about 8 months.

The potential benefits of this study are the opportunity to participate in a quit smoking program, which includes counseling and nicotine patch at no cost and (2) the opportunity to contribute to research that will allow us to learn more about ways to improve treatment for smokers and prevent the weight people gain after they quit smoking. The alternative to participating in this study is not to participate.

The most common risks of participation are mild side effects from wearing the nicotine patches (e.g., skin irritation) and nicotine withdrawal symptoms (e.g., irritability and trouble sleeping).

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 when reviewing the entire combined Informed Consent Form and HIPAA document and while completing the consent discussion. 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 a research study because you are interested in quitting smoking, report smoking at least 5 cigarettes a day for at least the past 6 months, and potentially meet other study criteria. 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, this consent document will inform you about the research study. The consent outlineswhat 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 may also decide to discuss it with yourfamily, friends, or family doctor. You may find some of the medical language difficult to understand. After reading the document you will have the opportunity to discuss the consent with a member of the research staff and ask the research staff, please ask the research staff to answer any

questions you may have. If you decide to participate, you will be asked to sign this form. You will be given a copy of the final combined informed consent and HIPAA authorization form for your records.What is the purpose of this research study?

The purpose of this research study is to better understand (1) why people gain weight when they quit smoking and (2) whether certain types of smoking cessation (i.e. quit smoking) counseling combined with the nicotine patch can help people quit smoking and gain less weight.

In addition to the main study described above, participants who are eligible for the main study and meet certain medication-related study conditions may also elect to participate in a microbiome sub-study.

Our bodies carry around trillions of microbes--bacteria, viruses, and other living things so tiny that we need a powerful microscope to see them. These microbes live in many places on and inside our bodies, such as the skin, the mouth, the nose, and the gut. While we still don't know how they do it, many of these microbes help to keep us healthy, while others contribute to disease. Similarly, changes in our health and diet can affect our microbes.

People and microbes both have DNA, the material that contains genetic instructions. The microbes' DNA affects how they live with each other and how they act in our bodies. Our own DNA also affects how we react to our microbes. All of the different kinds of microbes that live on and inside us, taken together, are called the "human microbiome."

The purpose of the microbiome sub-study is to examine how quitting smoking changes your naturally-occurring gut bacteria and whether these changes are linked to what you eat after you quit smoking.

How long will I be in the study?

Once your final eligibility has been confirmed, your participation in this study will last approximately 30 weeks (~8 months). We anticipate that this study will continue to recruit research participants for a period of 44 months. In addition to the main study, the microbiome sub-study will recruit research participants for a period of 8-10 months.

What am I being asked to do?

As displayed in the table on the following page, this study includes up to 11 in-person visits, 8 smoking cessation counseling sessions, 8 weeks of nicotine patch, and three 24-hour dietary recall assessments over the telephone or in person at 5 separate time points (a total of 15 assessments). During each 24-hour dietary recall, a member of the research team will contact you over the telephone during a predetermined time window to discuss your eating and drinking from the day before. If you are already scheduled to come to the Center for a study visit on the day of a 24-hour dietary recall, your dietary recall assessment may be completed in person instead of over the telephone. Each dietary recall assessment will take about 30-60 minutes. Further information about each study time point is provided in the "study activity table" and the text that follows.

In addition to the main study described above, participants who are eligible for the main study and meet certain medication-related study conditions may also elect to participate

in a microbiome sub-study during which you will be asked to provide three stool samples at three separate time points. We will prepare and study microbe DNA and metabolites (i.e., break down products and chemicals) from each of your stool samples.

If you are eligible and elect to participate in the sub-study, you will receive a stool sample collection kit and detailed instructions (written and verbal) about how to complete the self-collection of your stool sample within 24 hours ahead of three study time points: **Baseline Visit (Week -2)**, **Mid-Treatment 3 Visit (Week 4)**, and **End of Treatment Visit (Week 8)**. Stool samples will be self-collected at your home using the supplies included in the stool sample collection kit. You will be asked to return the stool samples to the Center during the visits listed previously or shortly thereafter. Under certain circumstances, we may permit you to ship your stool samples. In addition to providing stool samples, you will be asked about your use of antibiotics and the consumption of yogurt or other products that may affect the bacteria in your gut at in-person visits.

STUDY ACTIVITY TABLE				
Study Week	**Study Visit (Duration)**	**Activities**	**Nicotine Patch**	
			5-9 Cigs Per Day	**≥ 10 Cigs Per Day**
-3	Intake (~3 hours)	Measures to confirm study eligibility	[redacted]	
-2	Baseline (~3 hours)	Return a stool sample* Measures Computerized Lab Tasks Counseling Session 1 24-Hour Dietary Recalls		
-1	Pre-Quit (~2 hours)	Measures Counseling Session 2		
0	Target Quit Date (~1.5 hours)	Measures Counseling Session 3	Begin wearing patch 1 patch/day (14 mg)	Begin wearing patch 1 patch/day (21 mg)
1	Mid-Treatment #1 (~3 hours)	Measures Computerized Lab Tasks Counseling Session 4	1 patch/day (14 mg)	1 patch/day (21 mg)
2	Mid-Treatment #2 (~1.5 hours)	Measures Counseling Session 5	1 patch/day (14 mg)	1 patch/day (21 mg)
3	**NO VISIT**		1 patch/day (14 mg)	1 patch/day (21 mg)
4	Mid-Treatment #3 (~3 hours)	Return a stool sample* Measures Computerized Lab Tasks Counseling Session 6 24-Hour Dietary Recalls	1 patch/day (14 mg)	1 patch/day (14 mg)
5	**NO VISIT**		1 patch/day (14 mg)	1 patch/day (14 mg)
6	Mid-Treatment #4 (~1.5 hours)	Measures Counseling Session 7	1 patch/day (7 mg)	
7	**NO VISIT**		1 patch/day (7 mg)	
8	End of Treatment (~3 hours)	Return a stool sample* Measures Computerized Lab Tasks Counseling Session 8 24-Hour Dietary Recalls	[redacted]	
12	Follow-Up Visit #1 (~30 minutes)	Measures Saliva Sample** 24-Hour Dietary Recalls		
26	Follow-Up Visit #2 (~30 minutes)	Measures Saliva Sample** 24-Hour Dietary Recalls		

**Only participants who are eligible and elect to participate in the microbiome sub-study will be asked to provide a stool sample*

***Based on your smoking behavior, you may or may not be asked to provide a saliva sample*

Intake Visit (Week -3): The purpose of the Intake Visit is to familiarize you with the study procedures and risks, as well as to determine your final eligibility for the study. We anticipate that all of the activities for the Intake Visit will take about 3 hours.. The Intake visit includes the following tasks:

- Complete the study informed consent and HIPAA form in its entirety in order to participate in this research study. After reviewing the entire consent, you will have the opportunity to have a consent discussion with a member of the research staff via the telephone or in-person and 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.
- Further, to ensure the safety of research staff and participants, the urine sample may also be used to complete a Urine Cotinine assessment. Cotinine is a by-product of nicotine metabolism, or nicotine breakdown. The presence of cotinine in the urine sample will be used to confirm your smoking status. 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 cotinine test, 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.
- You may complete a breath alcohol concentration (BrAC) assessment. A breath alcohol reading greater than 0.000 will result in exclusion from the study.
- You may 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 5 parts per million to be eligible for the study.
- Complete a blood pressure measurement with study personnel. If your blood

pressure is higher than our safety cutoff, you will be deemed ineligible for the study.

- Have your height and weightmeasured.
- Complete a medical history form with a member of the research team and provide information on medications you are currently taking or recently discontinued in-person or over thetelephone
- Complete a brief IQ test (Shipley Institute of Living Scale) online using REDCap prior to coming into the center or in-person if the Principal Investigator grants permission. Please note you will not receive the results of this assessment.
- Complete paper and pencil questionnaires and a Program Referral Form.

- Complete a computerized lab task by rating how appetizing you find a set of pictures. In addition, you will select a preferred snack to "work for" over the course of the study.
- Schedule your Baseline Visit. After you complete the Baseline Visit, you will schedule the remainder of your visits and dietary recall telephone calls.

As you complete the tasks listed above, there is a chance you may not meet all of the study eligibility criteria. If this occurs, you will be deemed ineligible for the study. Study eligibility criteria have been established for data quality and/or safety purposes. If you successfully complete all of these tasks, you will receive $25.00 in cash for your time, which includes $5.00 for transportation compensation. If you are deemed ineligible at any point during the in-person portion of the Intake Visit, we will only compensate you $5.00 to cover your travel costs. No compensation will be given to those deemed ineligible prior to coming into the center for an Intake Visit.

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

- NOT use any other forms of nicotine besides the patches provided to you as part of this study (e.g., nicotine gum, nicotine spray, cigars, e-cigarettes, any type of vaped nicotine, lozenge, etc.).
- NOT use any study prohibited medications or recreational drugs as listed above.
- Notify us if you are prescribed a new medication (prior to taking first dose if possible).
- 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 should NOT participate in this study if you are pregnant or breast feeding.
- Notify the research staff about any medical concerns and/or symptoms.
- Attend ALL study visits as scheduled.
- Follow ALL study instructions as directed.

Baseline Visit (Week -2): The Baseline Visit will last about 3 hours. You will be instructed not to consume food or caffeine for 4 hours prior to the beginning of your scheduled visit. During the Baseline Visit you will complete the following procedures:

- Complete a CO assessment, answer items concerning marijuana use, and provide information on your daily smoking rate.
- Review use of any medications not previously reported.
- Have your weight measured.
- Complete paper and pencil questionnaires.
- You will be provided with a Boost® Nutritional Drink (8oz) to drink and then complete a series of food-related computer tasks (~30 minutes).
- Complete a standardized 30-minute wait period and complete a paper and pencil questionnaire.
- Complete your first smoking cessation counseling session.
- Schedule the remainder of your study visits and 24-hour dietary recall telephone calls. The first three of these recalls will be completed over the following week.

Pre-Quit Visit (Week -1): The Pre-Quit Visit will last about 2 hours. During the Pre-Quit Visit you will complete the following procedures:

- Complete a CO assessment, answer items concerning marijuana use, and provide information on your daily smoking rate.
- Review use of any medications not previously reported.
- Have your weight measured.
- If you required multiple blood pressure measurements during the Intake Visit, you will complete an additional blood pressure measurement.
- Complete paper and pencil questionnaires.
- Complete your second smoking cessation counseling session and receive your first supply of nicotine patches. This counseling session will prepare you for your upcoming target quit date (TQD), which will occur the following week. Your counselor will discuss the role of nicotine patch therapy in withdrawal symptom management and direct you on how to properly use the patch. Beginning on your TQD, if you smoke 10 or more cigarettes per day you will use the 21mg patch for the first 4 weeks, 14mg patch for the following 2 weeks, and the 7mg patch for the final 2 weeks. If you smoke 5-9 cigarettes per day you will use the 14mg patch for the first 6 weeks and the 7mg patch for the final 2 weeks. If you are unable to attend an in-person visit or you do not have enough patches to continue with your treatment schedule, additional supplies of nicotine patches may be mailed (authorized parcel service) or picked up if approved by the Principal Investigator. If nicotine patches are mailed, you must be available to sign for the delivery and receive the nicotine patches personally.

Target Quit Day Visit (Week 0): The Target Quit Day Visit will last about 1.5 hours. During the Target Quit Day Visit you will complete the following procedures:

- Complete a CO assessment, answer items concerning marijuana use, and provide information on your daily smoking rate.
- Review use of any medications not previously reported.
- Have your weight measured.
- Complete paper and pencil questionnaires.
- Complete your third smoking cessation counseling session, as well as provide information about your nicotine patch treatment.

Mid-Treatment #1 Visit (Week 1): The Mid-Treatment #1 Visit will last about 3 hours. You will be instructed not to consume food or caffeine for 4 hours prior to the beginning of your scheduled visit. During the Mid-Treatment #1 Visit you will complete the following procedures:

- Complete a CO assessment, answer items concerning marijuana use, and provide information on your daily smoking rate.
- Review use of any medications not previously reported.

- Have your weight measured.
- Complete paper and pencil questionnaires.
- You will be provided with a Boost® Nutritional Drink (8oz) to drink and then complete a series of food-related computer tasks (~30minutes).
- Complete a standardized 30-minute wait period and complete a paper and pencil questionnaire.
- Complete your fourth smoking cessation counseling session, as well as provide information about your nicotine patch treatment.

Mid-Treatment #2 Visit (Week 2): The Mid-Treatment #2 Visit will last about 1.5 hours. During the Mid-Treatment #2 Visit you will complete the following procedures:

- Complete a CO assessment, answer items concerning marijuana use, and provide information on your daily smokingrate.
- Review use of any medications not previouslyreported.
- Have your weight measured.
- Complete paper and pencil questionnaires.
- Complete your fifth smoking cessation counseling session, as well as provide information about your nicotine patch treatment.

Mid-Treatment #3 Visit (Week 4): The Mid-Treatment #3 Visit will last about 3 hours. You will be instructed not to consume food or caffeine for 4 hours prior to the beginning of your scheduled visit. During the Mid-Treatment #3 Visit you will complete the following procedures:

- Complete a CO assessment, answer items concerning marijuana use, and provide information on your daily smokingrate.
- Review use of any medications not previouslyreported.
- Have your weight measured.
- Complete paper and pencil questionnaires.
- You will be provided with a Boost® Nutritional Drink (8oz) to drink and then complete a series of food-related computer tasks (~30minutes).
- Complete a standardized 30-minute wait period and complete a paper and pencil questionnaire.
- Complete your sixth smoking cessation counseling session, provide information about your nicotine patch treatment, and confirm the dates and times of the three 24-hour dietary recalls to be completed over the followingweek.

Mid-Treatment #4 Visit (Week 6): The Mid-Treatment #4 Visit will last about 1.5 hours. During the Mid-Treatment #4 Visit you will complete the following procedures:

- Complete a CO assessment, answer items concerning marijuana use, and provide information on your daily smokingrate.

- Review use of any medications not previouslyreported.
- Have your weight measured.
- Complete paper and pencil questionnaires.
- Complete your seventh smoking cessation counseling session, as well as provide information about your nicotine patch treatment.

End of Treatment Visit (Week 8): The End of Treatment Visit will last about 3 hours. The End of Treatment Visit will be scheduled after you have completed your nicotine patch treatment. You should not attend the End of Treatment Visit still wearing a nicotine patch. You will be instructed not to consume food or caffeine for 4 hours prior to the beginning of your scheduled visit. During the End of Treatment Visit you will complete the following procedures:

- Complete a CO assessment or provide a urine sample for a cotinine assessment, answer items concerning marijuana use, and provide information on your daily smoking rate.
- Review use of any medications not previouslyreported.
- Have your weight measured.
- Complete paper and pencil questionnaires.
- You will be provided with a Boost® Nutritional Drink (8oz) to drink and then complete a series of food-related computer tasks (~30minutes).
- Complete a standardized 30-minute wait period and complete a paper and pencil questionnaire.
- Complete your eighth and final smoking cessation counseling session, provide information about your nicotine patch treatment, and confirm the dates and times of the three 24-hour dietary recalls to be completed over the followingweek.

Follow-Up Visits 1 (Week 12) and 2 (Week 26): Follow-Up Visits 1 and 2 will last about 30 minutes. During each of the Follow-Up Visits you will complete the following procedures:

- Complete a CO assessment or provide a urine sample for a cotinine assessment, answer items concerning marijuana use, and provide information on your daily smoking rate.
- Review use of any medications not previouslyreported.
- Have your weight measured.
- Complete paper and pencil questionnaires.
- Based on your smoking behavior, you may or may not be asked to provide a 5ml saliva sample (1 teaspoon) that will be used to examine metabolites or “break down products” of nicotine.
- Confirm the dates and times of the three 24-hour dietary recalls to be completed over the following week (or around the date of your scheduledvisit).

What are the possible risks or discomforts?

The likelihood and severity of the potential risks to you are described below. Overall, there is minimal risk for serious adverse reactions by enrolling in this research program. However, this research study may involve risks that are currently unforeseeable.

Nicotine Patch: Nicotine patches are a Food and Drug Administration (FDA) approved over-the-counter medication. In general, the nicotine patch is well tolerated by those who use it. The most frequent side effects reported by those using nicotine patches are listed below. These side effects tend to be mild.

- Nausea
- Vomiting
- Dizziness
- Weakness
- Rapid Heartbeat
- Irregular Heartbeat
- Skin Redness, Rash, or Swelling
- Itching, Burning, or Tingling at the patch site
- Heart Palpitations (noticeably hard or fast beats)
- Sleep Disturbances
- Vivid Dreams

We will closely monitor your side effects or medical concerns throughout the study. Any notable side effects or medical concerns will be presented to the Study Physician for instructions on how to best proceed with your treatment.

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

Nausea, vomiting, dizziness, weakness, and rapid heartbeat are side effects that occur rarely, but are most often caused by continuing to smoke while using the patch. You should also be aware of side effects such as difficulty breathing or a notable rash because these could be the symptoms of an allergic reaction. If any of these reactions occur, you may call the emergency contact (Study Physician) listed on page 1 of this form, members of the study team, and your doctor. You should always report any negative reactions you believe may be caused by the patch to the study team. If signs of nicotine overdose occur and you are currently smoking and using the patch, you will be counseled to reestablish a target quit day and gradually reduce your smoking rate again. Counselors have been specially trained to handle smoking relapse and to help prepare you for an additional quit attempt if necessary. We will not require that you remove the patch if you return to smoking over the treatment period unless you are experiencing side effects that concern you. You should not stop using the patch without discussing your symptoms with the Study Physician and study staff unless you experience severe or intolerable side effects.

Other nicotine patch risks can include risks to children and pets if the nicotine patches are not stored or disposed of properly. Unused and used patches have enough nicotine to poison children and pets. Keep the patches out of the reach of children and pets. Be sure to fold the sticky ends together when disposing of used patches. If a child or pet swallows a nicotine patch, seek professional help or contact a Poison Control Center right away.

A strict list of exclusionary criteria (conditions) will be used in this study to further limit the possibility of the side effects listed above and to protect your safety. If you present with a blood pressure of greater than 159/99 (either number) at the Pre-Quit Visit, we will not be able to give you patches, and you may be asked to obtain written permission from your personal physician to receive them. Please note if you are unable to receive patches at Pre-Quit you may still continue with the remainder of the study and receive all of the cessation counseling as scheduled.

Although the nicotine patch delivers nicotine (the addictive ingredient in cigarettes), it is at a lower level than the nicotine delivered when smoking a cigarette. Thus, the level of nicotine in your body from using the nicotine patch is lower than if you were smoking. There is no evidence of addiction to the nicotine patch when used as part of a comprehensive smoking cessation program such as this one. Using the nicotine patch is less harmful to your health than cigarette smoking.

Withdrawal Syndrome: People who quit smoking may exhibit a pattern of symptoms related to withdrawal from nicotine which you may or may not recognize. These symptoms may include: anger, irritability, frustration, anxiousness or nervousness, depressed mood or sadness, cravings for nicotine, difficulty concentrating, appetite change and weight gain, insomnia or other sleep problems, restlessness, impatience, constipation, dizziness, coughing, nightmares, nausea, sore throat, headache, muscular pain, or fatigue. Eliminating the risk for these symptoms would not be possible, although in most cases these events are short-lived and have low intensity, lasting for 1-2 weeks. The study team is trained to recognize these symptoms and will educate you about reducing them.

Food Allergies: You will be provided with nutritional shakes and either potato chips or milk chocolate as part of your participation in this research trial. The risk of you experiencing an allergic reaction to any of the ingredients in these commercially available food products will be reduced by excluding those participants with the relevant food allergies. In addition, we will double check with you that you don't have any of the exclusionary food allergies prior to giving you any of these food products.

Psychological Distress: Some people can experience anxiety and other types of general distress when they complete assessments and smoking cessation counseling. These issues are typically caused by discussing feelings and attitudes about smoking or from learning about the risks from smoking. These reactions are usually very mild and typically diminish with time. They do not usually cause major emotional distress. The research staff that administer the assessments and counseling to you are trained to help you should you experience any concerns.

Potential Loss of Confidentiality: Every attempt will be made by the Investigator and the study team 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 or identified in this combined 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: The safety of nicotine replacement medicine (i.e. nicotine patches) for an unborn baby is unknown, so females should not become pregnant while in this study. Women in the study should not nurse a baby. If you are a woman, you must agree to use an adequate form of contraception or abstain from sexual intercourse for the duration and for at least one month after the end of the study. If you are pregnant or breast feeding, you should not participate in this study. If you become pregnant during the study, you should notify the research staff immediately and you will be withdrawn from the study. You will be asked to self-administer a pregnancy test at today's Intake Visit.

Stool Samples: If you are participating in the microbiome sub-study, you will be asked to provide stool samples. Collecting stool may contain germs that spread disease. You will be reminded to carefully wash your hands and use the gloves we will provide to you to avoid spreading infection. Some people may feel uncomfortable or embarrassed using the stool sample collection kit. There should be no pain while collecting the stool sample. However, if you are constipated, straining to pass stool may be painful.

Genetic Testing: If you are participating in the microbiome sub-study, this research will include genetic analysis of your stool sample. We will analyze the DNA from your stool (microbe) samples by a process called "sequencing," which means reading out the complete genetic code in the sample. Although your stool samples will be labeled with code numbers and not your name, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.

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?

By participating in this research study, you will have the opportunity to participate in a smoking cessation program, which includes counseling and nicotine patch at no cost. Therefore, you will have the opportunity to quit smoking completely or reduce your amount of smoking. Additionally, you will be contributing to research that will allow us to learn more about ways to improve treatment for smokers and prevent the weight people gain after they quit smoking.

What other choices do I have if I do not participate?

The alternative to participation is to decide not to enroll in this study. If you choose not to enroll in this study, but are still interested in quitting smoking, we can provide you with information on other smoking cessation treatment programs at our Center or in the Philadelphia area.

Will I be paid for being in this study?

Because we appreciate you donating your time to contribute to this research and to help cover expenses related to your participation (i.e., travel), you will have the opportunity to receive up to $590.00 per the study payment table below for completing the study requirements and procedures outlined in this consent form. You will be compensated in cash at the end of each in-person visit you attend as per the study payment table below. No compensation will be provided if you fail to complete all three 24-hour dietary recalls ($30.00 for completing each set of 3) at each of the five assigned time points. You may decide to receive the compensation you earn for completing the 24-hour dietary recalls in-person or via a check that will be mailed to your residence. As noted earlier, if you are deemed ineligible at any point during the Intake Visit today, we will only compensate you $5.00 to cover your travel costs.

If you are eligible and elect to participate in the microbiome sub-study, you will earn $25.00 for each stool sample you provide per the study instructions, as well as a $25.00 bonus for returning all 3 stool samples as instructed.

Study Payment Table

Study Time Point/ Activity	Compensation	Bonus	Travel Reimbursement	Total
Intake	$20.00		$5.00	$25.00
Baseline	$20.00		$5.00	$25.00
Baseline Stool Sample [1]	$25.00		N/A	$25.00
24-Hour Dietary Recalls (3) [2]	$30.00		N/A	$30.00
Pre-Quit	$20.00		$5.00	$25.00
Target Quit Day	$20.00		$5.00	$25.00
Mid-Treatment #1	$20.00		$5.00	$25.00
Mid-Treatment #2	$20.00		$5.00	$25.00
Mid-Treatment #3	$20.00		$5.00	$25.00
Mid-Tx. #3 Stool Sample [1]	$25.00		N/A	$25.00
24-Hour Dietary Recalls (3) [2]	$30.00		N/A	$30.00
Mid-Treatment #4	$20.00		$5.00	$25.00
End of Treatment	$35.00		$5.00	$40.00
End of Treatment Stool Sample [1]	$25.00	$25.00 [3]	N/A	$50.00
24-Hour Dietary Recalls (3) [2]	$30.00		N/A	$30.00
Follow-Up #1	$45.00		$5.00	$50.00
24-Hour Dietary Recalls (3) [2]	$30.00		N/A	$30.00
Follow-Up #2	$45.00		$5.00	$50.00
24-Hour Dietary Recalls (3) [2]	$30.00		N/A	$30.00
			TOTAL	Up to $590 [4]

[1] Only participants who are eligible and elect to enroll in the microbiome sub-study will provide stool samples

[2] You must complete <u>all three</u> 24-hour dietary recalls to receive compensation ($30.00) at each of the 5 assigned time points.

[3] Eligible participants who enroll in the microbiome sub-study and provide all 3 stool samples as instructed will receive a $25.00 bonus.

[4] Total does <u>NOT</u> include payments that may be earned during certain computer tasks.

Please note in order to participate in this study, you must provide your social security number, name, and address on a W-9 tax form because the University of Pennsylvania (UPENN) is required to report to the Internal Revenue Service (IRS) any total payments for participation in research studies at UPENN that exceed a total of $600 in a calendar year. All check payments must be processed through the Accounts Payable Department of the University of Pennsylvania and will require 4 to 6 weeks to arrive at the address you record on the W-9 tax form. You will complete the W-9 tax form at the end of today's visit.

Will I have to pay for anything?

There will be no charge to you for participating in this research study. 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, or if your insurance agrees in advance to pay.

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 listed on page one of this form.

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. 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 Sponsor, or the FDA without your consent because:

- The Primary 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.
- The funding sponsor, the study Principal Investigator, or the FDA has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care or participation in other research studies at our center.

Who can see or use my information? 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. If this study is reviewed by the FDA, they may have access to your research records.

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.
- Social security number (documented on the W-9 form)
- Personal medical history
- Counseling sessions may be recorded (audio) for training purposes to ensure every participant is receiving the same standard of counseling. You will be told if a counseling session is being recorded. The recording will be deleted after it is reviewed.
- Results from all questionnaires, tests, or procedures (including information on your metabolites or "break-down products" of nicotine from saliva samples)
- Microbe and human DNA sequencing data and information on metabolites from your stool samples (microbiome sub-study only)

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.

What may happen to my information and samples collected in this study?

Collection of Identifiable Specimens

If you are participating in the main study or microbiome sub-study, your saliva samples and stool 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, pay you, or to give any compensation to you or your family.

Whole genome sequencing will not be conducted on your saliva samples. If you are also participating in the microbiome sub-study, whole genome sequencing will be conducted on your stool samples. Whole genome sequencing involves analyzing your entire personal genetic code.

Future Use of Data and/or Specimens

If you are only participating in the main study, your information and samples will not be stored or shared for future research purposes.

If you are participating in the microbiome sub-study, we would like to store your stool 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 stool

samples, but the information and stool samples that you provide could be useful to future researchers by improving the understanding of health and disease, improving health care, more safe or more effective medical therapies, and developing new scientific knowledge. 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.

Your information and stool 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 stool 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 stool 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 stool samples to be maintained for use in future research. It is possible that your stool 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, to pay you, or to give any compensation to you or your family. Additionally, individual research results obtained as part of future research will not be shared with you. Note that most uses of biospecimens or information do not lead to commercial products or to profits for anyone.

Your identifiable information and stool samples will be stored for future research purposes only. Your information and stool 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 seeking your consent in the future, as permitted by law. The future use of your information and stool samples only applies to the information and stool samples collected during this study.

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 have access to your information for this research study:

- The Study Investigators and the Investigator's study team (other University staff associated with the study)
- The University of Pennsylvania Institutional Review Boards (the committees charged with overseeing research on human subjects) and University of Pennsylvania Office of Regulatory Affairs
- The University of Pennsylvania Office of Clinical Research (the office which monitors research studies)
- Authorized members of the University of Pennsylvania and the University of Pennsylvania Health System and School of Medicine workforce who may need to access your information in the performance of their duties (for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.).
- The Penn Metabolomics Core (if you are participating in the microbiome sub- study, the group that will be analyzing your stool samples for metabolites)

Who, outside of the School of Medicine, might receive my information?

- The PennCHOP Microbiome Program - CHOP Microbiome Center (if you are participating in the microbiome sub-study, the group that will be sequencing your stool samples, which means reading out the complete genetic code in the sample)

<u>Oversight and/or funding organizations</u>

- National Cancer Institute (NCI)/ National Institutes of Health (NIH)
- The FDA
- The Office of Human Research Protections

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. This does not mean that all personal identifying information is being disclosed. Generally, if information has to be released it contains only initials and birthdate or only a unique number or code, not complete contact information.

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 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?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization 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 research 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 with any questions, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research 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.

A copy of this consent form will be given to you.

Name of Subject (Please Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Please Print)	Signature	Date

Microbiome Sub-Study Participation*:
Only applicable when the sub-study is actively recruiting

Office Use Only: Check if sub-study is NOT actively recruiting
_____Staff Initials

Check **YES** record your initials if you consent to participate in the microbiome sub-study that was described to you above within this Informed Consent From. Please check **NO** and record your initials if you **do not** wish to participate in the microbiome sub-study.

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

NOTE: Providing consent to participate in the microbiome sub-study **does not** mean you will meet the necessary conditions to be eligible to participate. Only eligible participants who meet the eligibility criteria for both the main study AND sub-study may participate in the microbiome sub-study.

Use of your Information and Stool Samples for Future Research:

Office Use Only: Check if sub-study is NOT actively recruiting
_____Staff Initials

****Only applicable when the microbiome sub-study is actively recruiting and the participant elects to participate in the sub-study***

If you elected to participate in the microbiome sub-study, please check **YES** and record your initials if you give permission for us to retain your information and store your stool 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 stool samples from this study for use in future research.

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