GeoScan and Remote Geo Smoking Study: Neural and Behavioral Correlates of Smokers' Exposure to Retail Environments

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Geo Smoking Study Informed Consent and HIPAA Authorization Form

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Research Study Summary for Potential Participants

As someone who regularly smokes tobacco cigarettes, you are being invited to participate in this research study.The purpose of the study is to learn more about smokers' experiences and behavior in the places where they regularly spend time and in specific retail stores.

If you agree to join the study, you will be asked to actively complete study tasks daily for approximately 6 weeks:

- 3 Online survey sessions: (30-60 minutes each) You will be asked to complete questionnaires, take a urine test that measures how much you smoke, set up your mobile phone with study apps, submit the data from these apps, and practice the tasks you will be asked to do in between sessions
- Mobile phone surveys: We will also ask you to install a survey app on your mobile phone that will send you 4 very short surveys (less than 1-minute each) throughout the day, asking about your smoking behavior or how you are feeling.
- Location tracking: As we are interested in your dailyexposure to certain environments, we will ask you to install a location-tracking application (Google Maps) on your mobile phone that will track your location throughout the day between sessions.
- Store purchases: You may also beasked to use a study-provided payment card to make small purchases at a specific kind of retail store (such as CVS or 7-Eleven) 5 times per week for up to 4 weeks.

The total possible payment for the study is $500, which includes $60 to spend onstore purchases. Other than this payment, there is no direct benefit to you for participation. The most common risks of participation are a potential negative impact on your smoking behavior; potentially increased exposure to different kinds of advertising, including tobacco ads; and a risk of an unintentional breach of confidentiality about your information recorded in the surveys or through the location tracking app.

Your participation in the Geo Smoking study is voluntary, which means you are free to decline or stop participation in the study at any time. Your alternative to being in the study is to not be in the study. You should only participate ifyou completely understand what the study requires and what the risks of participation are. This information is covered in greater detail in the rest of this document, but you should also 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 research participant at any time before, during or after participation, please contact the study staff listed above or the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

Research study consent form

Invitation to participate

You are being asked to take part in a research study. This is not a form of treatment or therapy. It is not supposed to detect a disease or find something wrong. Your participation is voluntary, which means you can choose whether or not to participate. Before you make a decision, you will need to know the purpose of the study, the possible risks and benefits of being in the study, and what you will have to do if you decide to participate. All this information is

provided in this form. Please read it carefully.

If you do not understand what you are reading, do not agree to participate. Please feel free to ask researchers listed above, or with whom you are in contact about this study, to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to sign this form electronically before you start the study.

What is the purpose of the study?

The purpose of the study is to learn more about smokers' experiences and behavior in the places where they regularly spend time and in specific retail stores.

In some research studies, the investigators cannot tell you exactly what the study is about before you participate inthe study. We want you to behave as naturally as possible while you are completing tasks in this study. For this reason, we will describe the tasks in a general way, but we can't always explain all the details about why we are asking you to complete the tasks until after you complete the study. When you are done, we will explain why we aredoing this study, what we are looking at, and any other information you should know about this study. You will also be able to ask any questions you might have about the study's purpose and the tasks you did. Although we may not be able to explain the full purpose of the study until after you complete the tasks, there are no additional risks beyond those described in this consent form.

Why was I asked to participate in the study?

You are asked to join this study because you smoke tobacco cigarettes and you expressed interest in participating inthis study.

How long will I be in the study?

If you agree to join the study, you will be asked to actively complete study tasks (described in detail below) for approximately 6 weeks, starting when you sign this consent form.

We may contact you (via information you have already provided, such as your email address or phone number), during or after the study, to clarify the information that you have agreed to provide as part of the study or to provideor request additional information that is related to the study. You will always have the ability to leave the study and/or opt out of future contact.

How many other people will be in the study?

Approximately 400 other people will participate in this study.

What will I be asked to do?

3 online survey sessions: The self-guided surveys can be completed at the location of your choosing on an electronic device of your choosing (laptop or desktop computer, phone, or tablet). We ask that you set aside a block of time to complete each survey session in one sitting in a quiet room, where you won't be distracted.

During all 3 of the online sessions, you will be asked to provide more information about yourself and to complete various surveys asking your opinions on topics such as health, people in your social network, smoking, media, and retail outlets. To confirm that you are a smoker, we will also ask you to take a urine test at home to measure the level of cotinine (a nicotine byproduct) in your system, and submit a picture of your results as part of the session.

In addition to questionnaires and urine tests, here's what you can expect from each online session:

> Online Session 1 (30-60 mins total): You will be given step-by-step instructions to set up your smartphone with study applications, practice the brief mobile phone surveys, and get instructions for the next 2 weeks.
> Online Session 2 (30-45 mins total): You will be given step-by-step instructions to download and submit your location history, updateyour study applications, practice the weekly mobile phone surveys and store entry tasks (if required), and get instructions for the next 4 weeks.
> Online Session 3 (30-45 mins total): You will be given step-by-step instructions to download and submit your location history, uninstall study applications, and get more information about the study.

Mobile phone surveys: Approximately 4 times per day, you will receive a push notification on your mobile phone with a very short survey to be completed as soon as possible when you receive it. These messages will be sent via the

LifeData (aka “RealLife Exp”) app, a third-party application. You will be guided through the download of this application during the first online survey. Each mobile survey will consist of several brief questions asking about your smoking behavior or how you are feeling. Once per week for last 4 weeks of the study, we will send you a link to an additional, longer survey that should take approximately 5 minutes to complete.

Location tracking: Because we are interested in your natural daily exposure to different locations around the city, you will be asked to track your mobility during the study period through Google Timeline and to share your data with the study team. If you do not have the Google Maps app on your phone already, you will be asked to download it for this purpose and to allow location services through that app. Installing Google Maps app is necessary for participation in the study. We will guide you through uninstalling the app from your phone at the end of the study if you would like us to do so.

Store purchases: You may be asked to enter an assigned retail chain (such as CVS or 7-Eleven) 5 times per week for up to 4 weeks, and to make a purchase using a study-provided funds on a Greenphire ClinCard, a reloadable debitcard. If you are asked to enter a specific kind of store, we will ask you to send the study coordinators a photograph ofyour receipt every day, to confirm that you have made a purchase at the store.

What are the risks?

Surveys and location tracking: These procedures are of minimal risk. It is possible that study participation will have a negative impact on your smoking behaviors, as well as potentially increase your exposure to different kinds of advertising, including tobacco ads. The surveys may be an inconvenience, or cause tiredness. If you are uncomfortable or tired, you may stop and remove yourself from the study at any time for whatever reason. There may be a risk of an unintentional breach of confidentiality about your information recorded in the surveys or through the location tracking app. Please note that the location tracking application will collect information about where you go at all times while it is turned on, but we will only be able to see that information once you submit it to us. In other words, we are not able to see where you are in real-time. We are only interested in very specific pieces of this location data, for example, as it relates to your exposure to certain retail environments. However, the final dataset might include sensitive information about your location, for instance during personal visits or illegal behavior. We will make every effort to prevent any unintentional breach of confidentiality (see section below on maintaining confidentiality), and as noted below, this research is covered by a Certificate of Confidentiality. Your name and other identifiable information will be removed from all information we collect, and this information will be labeled with a unique identification code.

Store entry: For the duration of the COVID-19 pandemic, entry into retail stores as part of this study may increase your risk of being exposed to and spreading SARS-COV-2, the virus that causes COVID-19 disease. That is why you must provide the study team with a picture of your COVID-19 vaccination card to participate in this study (your vaccine card must show that you are fully vaccinated, according to the most updated standards). We ask that you abide by the most up-to-date COVID-19 safety guidelines, which may include mask wearing, social distancing, booster vaccination, and other relevant recommendations from the Center for Disease Control and Prevention (CDC). To further reduce transmission risks, KN95 or N95 masks are included in the box of study materials that we provide you with. These masks may be worn at any time, including while you are completing study tasks such as entering retail stores.

How will I benefit from the study?

There is no direct benefit to you for participation. We hope that the information learned from this study may benefit other people and further science by helping us to better understand the relationship between the brain, behavior, and exposure to daily environments.

What other choices do I have?

Your alternative to being in the study is to not be in the study.

What happens if I do not choose to join the research study?

Your participation is completely voluntary, and you may withdraw at any time without penalty.

When is the study over? Can I leave the study before it ends?

The study is expected to end after all participants have completed all surveys, and all the information has beencollected. Your participation in the study may be stopped without your consent for the following reasons:

The PI feels it is best for your safety and/or health - you will be informed of the reasons why. You have not followedthe study instructions. The PI, the sponsor or the Office of Regulatory Affairs at the University of Pennsylvania can stop the study anytime. You have the right to drop out of the research study at any time during your participation. There will be no negative consequences for your withdrawal.

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.

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. You do not give up your legal rights by signing this form. If you think you havebeen 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 at the beginning of this consent form.

Will I have to pay for anything?

If we ask you to make small purchases at retail outlets, we will provide adequate funds on a reloadable debit cardfor you to make these purchases. However, you will not be reimbursed for other study-related costs that you may incur, such as parking, or text messaging charges. Standard text message charges may apply from your wireless provider, depending on your text message plan.

Will I be paid for being in this study?

You will be paid through a Greenphire ClinCard, a reloadable debit card. You will receive a physical ClinCard in your box of study materials, which can be used to make in-store purchases or at an ATM. If you lose your physical card,you will receive a virtual replacement card, which can be used to make purchases at merchants that accept digital Visa cards or at banks and ATMs to withdraw cash if you transfer the funds to your personal bank account. You will be paid $95 for completing the initial intake call, Screening Survey B, and the first online session. If you are excluded at the beginning of Online Session 1 and are thus ineligible to finish the session, you will still receive $75 for the screening tasks that you already completed. If you are eligible to continue after Screen Survey B and Online Session 1, you will receive $20 each for the second and third Online Sessions (total for all Online Sessions = $135). You can receive up to $305 for the other tasks that you complete, such as responding to daily phone surveys, keeping the location-tracking app active on your phone, and submitting your receipt photographs. If you withdraw or are excluded after completing Online Session 1, you will receive prorated payment for thestudy tasks that you have completed before exclusion or withdrawal. If we ask you to make regular visits to a retail location for purchases, you willbe able to keep the goods purchased from your assigned store —these purchases will be funded through an additional $60 deposited onto your ClinCard. We will not ask you to exceed $60 in purchases. If you are not assigned to enter a store, you will receive the $60 on your ClinCard at the last appointment. The total possible benefit is thus $500.

In order to be compensated for your participation in this study, you must provide your Social Security Number. You will be prompted to provide your Social Security Number during Online Session 1. Pleasenote that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

What information about me may be collected, used or shared with others?

Only study staff members will have access to identifiable information. Your information will be collected and shared among research staff in our laboratory for study purposes. We will collect information such as:

Your name; address; date of birth; telephone numbers; electronic mail addresses; social security number Physical measurements like your height; weight; physiological measures of smoking Personal history including cigarette smoking, as well as other medical conditions Results of study procedures and measurements like geolocation tracks

Why is my information being used?

Your information, 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

How will my personal information be protected during the study?

We want you to be aware that research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. Authorities also cannot provide any information, documents, or samples from this study as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. All data will be coded with a study identification number unique to each study participant. Any documents or digital records linking a participant's study identification numbers to their personal identification information will be stored in a password-protected, secure database available only to study staff. Google Maps and Timeline standardly track the user's mobility patterns. These apps might already be active on some participants' phones as they come pre-installed on Android phones. Google will be able to access and use the mobility data collected through these apps per their data agreement with the user. The data each participant shares with the study team will be coded, kept confidential, and stored securely.

What may happen to the information about me that is collected for this study?

Your information will be de-identified. De-identified means that all identifiers have been removed. The information could be stored and shared for future research in this de-identified fashion. The information may be shared with other researchers within Penn, or other research institutions. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. 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 on this study.

Your geolocation data will be stored and may be used for future research. Although researchers cannot readily ascertain your identity from your geolocation data, it may be possible to indirectly identify elements of your identitylike your home address. As described above, we will do our best to make sure that the personal information obtainedduring the course of this research study will be kept private. Data will be stored securely on password-protected, secure servers and will only be shared with other researchers following approval by the Institutional Review Board.

Who may use and share information about me?

Research teams at the Annenberg School for Communication and the University of Pennsylvania, and the College of Global Public Health at New York University, collaborate on this project and may use or share your information for this research study.

Who, outside of the study team, might receive my information?

National Institutes of Health (Funding Sponsor) The Office of Human Research Protections The study data and safety monitoring board Annenberg School for Communication IT staff may view your information during data maintenance work on our lab's database Our business administrator will have access to your name and the last four digits of your social security number for the purpose of reimbursement of your participation Greenphire, the company which manages the ClinCard payment portal, will have access to your full name, birthdate, social security number and address for payment purposes, and, optionally, phone number and email address for payment alerts. Trained Communication Neuroscience Lab members may view coded data for research purposes or your contact information if you indicate explicitly that you would like to be contacted for future studies Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB Other authorized personnel at Penn, including offices that support research operations.

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.

We will adhere to the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NOT-OD-16-149). This means that the project will be registered in ClinicalTrials.gov prior to the start of the study, and that we will report aggregate study results on ClinicalTrials.gov according to NIH policy requirements and timeliness.

How long may the study team 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 study team may not re-use or re-disclose informationcollected 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 What if I decide not to give permission to use and give out my information?

You will not be able to participate 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 study team to use and disclose personal health information collected about you on a limited basis 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 document, 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 participate. Your agreement to participate in this study 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. If you have any questions or if there is something you do not understand, please ask. You will receive a copy of this consent document.