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

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Geo Smoking Study
Addendum to the Informed Consent and HIPAA Authorization

Study Title: Geo Smoking Study

Principal Investigator: Dr. Emily Falk

IRB Number: 850796

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We are inviting you to take part in an additional study component, which was not included in the consent form you originally signed. You are being given this opportunity because you recently participated in the remote Geo Smoking Study and you expressed interest in participating in the in-person component of this study at the University of Pennsylvania. Your participation is voluntary, which means you can choose whether or not to participate.

This consent form is in addition to the consent and HIPAA authorization you already provided for this research study. The additional data/samples collected will be covered by the HIPAA authorization you already provided for the main study. Except as stated below, no changes are made in the information described in the original consent document. Please read this consent addendum carefully and take your time making your decision. Please ask the study staff to explain any words or information that you do not clearly understand.

What will I be asked to do for the additional research session?

You will be asked to attend an in-person session at the University of Pennsylvania campus in Philadelphia for approximately 2 hours. During the session, you will be asked to fill out forms on a computer and/or on paper, provide a urine sample for testing, view and rate images in a brain imaging (fMRI) scanner, and follow COVID-19 safety measures. Please see the sections below for more detail.

Urine Tests: During the appointment, we will ask you to provide a urine sample for the following purposes:

(1) To confirm that you regularly smoke cigarettes, by measuring nicotine byproducts in your system (this is the same urine cotinine test that you did on your own in Session 1).

(2) To test for other drugs in your system that could change your brain activity, including cannabinoids (marijuana), cocaine, opiates/morphine, amphetamines, methamphetamines, methadone, barbiturates (secobarbital), benzodiazepines (oxazepam), phencyclidine (PCP), MDMA (ecstasy), oxycodone, and buprenorphine.

(3) Optional: If you think you might be pregnant, we will provide a urine pregnancy test free of cost.

We will record the results of these tests in our secure participant database. *You will be excluded from participation if your urine sample results in (1) a negative (<200 mg/L) cotinine test, indicating that you do not smoke regularly, (2) a positive test for any of the drugs mentioned above, with the exception of cannabinoids (marijuana), or (3) a positive pregnancy test.*

1-hour MRI Scan: During the appointment, you will have a series of pictures taken of your brain produced using a Magnetic Resonance Imaging (MRI) device. This device uses large magnets and radio waves to take pictures of your brain. You will be asked to lie on your back in the machine and remain still for approximately one hour, while the MRI takes pictures. During this hour, you will see images on the screen and will be asked to make choices or ratings based on what is presented. You will complete these tasks with the use of a hand-

held control that you will hold in your right hand, because speaking your responses out loud would cause your head to move too much. The image rating task will be almost identical to the one that you completed online during Sessions 2 and 3, but we will still review the instructions in detail and give you a chance to practice before the scan. Some of the MRI pulse sequences and equipment components are not FDA-approved but are considered to pose no more than minimal risk.

Please note: The MRI performed under this protocol is not for medical purposes, and the images are not planned to be interpreted by a physician.

W-2 Form: During the appointment, you will be required to sign a W-2 tax form to receive your additional payment. Our business office requires this information from participants that complete study tasks in-person. In order to fill out this form, you will need to provide your social security number, which we already have documented from your previous participation in the online study.

COVID-19 Safety Measures: During the COVID-19 pandemic, you may be required to do the following at or before the in-person study session:

(1) Answer COVID-19 symptom screening questions
(2) Undergo a temperature check
(3) Wear a mask that we provide

Note: Your in-person appointment may be rescheduled or canceled by the study team in the event that you do not meet the COVID-19 screening requirements necessary to enter the testing facilities, including but not limited to:

(1) Reporting any COVID-19 related symptoms
(2) Reporting any recent positive COVID-19 test
(3) Reporting any recent interactions with others who have tested positive for COVID-19

What are the possible risks or discomforts of participating in this additional session?

The researchers have taken steps to minimize risks involved with this study. Even so, you may still experience some risks related to your participation, even when researchers are careful to avoid them.

Urine tests: These procedures are of minimal risk. As with all of the information collected for this study, there may be a risk of an unintentional breach of confidentiality about your information recorded in the surveys, urine tests, and brain scan. However, the information collected during this session will be held to the same rigorous standards of confidentiality and data security, which were explained in the main consent document that you signed at your first appointment. This includes the protection of a Certificate of Confidentiality from the National Institutes of Health, which means that no authority will have a legal means of accessing your drug test results or any other personally sensitive data without your permission.

MRI Scan: MRI is a non-invasive procedure that collects a set of images of your brain by measuring the change in blood flow related to neural activity without the exposure of radiation.

Mild Discomfort: The most common side-effects experienced in an MRI scanner are due to mild feelings of claustrophobia, mild stiffness (after lying still for a prolonged period), or mild feelings of discomfort due to the loud noise of the scanning machine. We will provide you with protective earplugs and make every attempt to ensure your comfort with blankets, leg rests, etc. during your time in the scanner. Some of the pulse sequences and/or RF coils are not FDA approved but are considered to pose no more than minimal risk. Some studies,

like this one, have the potential to cause “peripheral nerve stimulation” (PNS). PNS is a light touching sensation on the skin surface, lasting only for a few seconds. It may cause mild discomfort, but it is not harmful to you.

Flying Objects: The greatest risk of MRI is a magnetic object flying through the air toward the magnet and hitting you. To reduce this risk we require that all people involved with the study remove all magnetic metal from their clothing and all magnetic metal objects from their pockets. No magnetic metal objects are allowed to be brought into the magnet room at any time except by approved personnel. In addition, once you are in the magnet, the door to the room will be closed so that no one inadvertently walks into the room.

Medical Implants and Foreign Bodies: There is also a potential risk of MRI for subjects with medical implants or other metallic objects in their body. All subjects undergoing MRI scanning must complete a screening evaluation risk in advance of the study for the presence of medical implants or other foreign bodies that could pose an injury. Every effort will be made to insure that disclosed implants or foreign bodies do not pose a risk to subjects. In cases where there is insufficient information to evaluate the risks associated with an implant or foreign body, the MRI study will not be allowed to proceed.

Pregnancy: Although there are no known risks related to MRI on pregnant women or a fetus, there is a possibility of yet undiscovered pregnancy related risks. Since there is no possible benefit from participating in this protocol for a pregnant woman, we will exclude pregnant women.

Incidental Findings: This fMRI is not a clinical scan. It is possible that during the course of the research study, the research staff may notice an unexpected finding(s). Should this occur, the finding(s) will be considered by the appropriate personnel and the PI will inform you if necessary. These possible finding(s) may or may not be significant and may lead to anxiety about your condition and to further work-up by your physician.

COVID-19: For the duration of the COVID-19 pandemic, an in-person visit with researchers may increase your risk of being exposed to and spreading SARS-COV-2, the virus that causes COVID-19 disease. To reduce transmission risks, the study team will ask you to follow the safety measures listed in the previous section. The study team will take precautions during study sessions including requiring study staff to be vaccinated against COVID-19, wear masks, follow sanitation procedures, and abide by the most up-to-date COVID-19 safety guidelines provided by UPenn (e.g., recommendations from the Philadelphia Department of Public Health).

What are the benefits of participating in this additional session?

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.

Will I be paid for participating in this additional session?

You will be paid $95 on your Greenphire ClinCard for completing the in-person scanning session. The total possible benefit of your overall study participation is thus $595.

If you are unable to be scanned because you are uncomfortable or experience claustrophobia in the scanner, or cannot fit, you will still be paid for the full session. If you must be excluded for other reasons or if we have to reschedule after your arrival for the in-person session you will be paid $15 for your time via your ClinCard or

petty cash. If your fMRI scanning session exceeds the expected 2 hour duration you will be paid an additional $15/hour for extra time spent at the scan ($7.50 for every half hour over 2 hours).

Please note 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.

Are there any additional costs for participating in this additional session?

You will not be reimbursed for any costs that you may incur related to text messaging charges. Standard text message charges may apply from your wireless provider, depending on your text message plan.

Incurred out-of-pocket travel expenses may be reimbursed up to $75 total. Travel reimbursement covers costs of parking, public transportation, rideshare services, and mileage if driving. For mileage, we will reimburse $0.655 per mile, which is the current national rate set by the IRS. We will not reimburse separately for gas, as this is covered by mileage reimbursement. Addresses must be provided for the calculation of mileage, and receipts (if obtainable and at least $25) must be presented for all other out-of-pocket travel expenses. Upon receipt validation or mileage calculation, you will be reimbursed through your Greenphire ClinCard.

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.

SIGNING BELOW INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, THAT YOU ARE 21 YEARS OF AGE OR OLDER.

Signature of Participant _____

Print Name of Participant _____

Date _____