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

DATE: 23-Nov-2020
TO: Anupreet K Sidhu
CC: Souprountchouk, Valentina

RE:
IRB PROTOCOL#: 843703
PROTOCOL TITLE: Evaluation of the new FDA warning labels

SPONSOR: NATIONAL INSTITUTES OF HEALTH
REVIEW BOARD: IRB #7

IRB AMENDMENT: NOTICE OF APPROVAL

Dear Dr. Sidhu,

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

Consistent with the regulations set forth in 45 CFR 46.109(f), continuing review of this research is not required. IRB approval of this protocol will not expire and continuing review applications should not be submitted. However, you are still required to submit modifications and reportable events to the IRB for review.

The documents included with the application noted below are approved:

-HSERA Application, confirmation code: dcgdejhb, submitted on 11/10/2020

NOTE: Approval by the IRB at this time DOES NOT constitute authorization to initiate or continue in-person research during the COVID-19 pandemic. **Please review Guidance on Notification to the IRB of In-Person Research Resumption During Phase II (Effective 7/13/2020) on the IRB website here for further details:** https://irb.upenn.edu.

ONGOING REQUIREMENTS:

- You must obtain IRB review and approval under 45 CFR 46 if you make any changes to the protocol, consent form, or any other study documents

subject to IRB review requirements. Implementation of any changes cannot occur until IRB approval has been given.

- Reportable event, such as serious adverse events, deviations, potential unanticipated problems, and reports of non-compliance must be reported to the IRB in accordance with Penn IRB SOP RR 404.
- When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

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

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

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

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

UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT INFORMED CONSENT FORM

Protocol Title:	Evaluation of new FDA tobacco warning labels
Principal Investigator:	Anupreet Sidhu, Ph.D. 3535 Market Street, 4th floor Philadelphia, PA 19104 215-746-3782 After hours 650-892-2720
Emergency Contact:	Anupreet Sidhu **347-690-0340**

Why am I being asked to volunteer?

You are being invited to participate in this research study about cigarette warning labels because you are a cigarette smoker. You can choose whether or not you want to participate in this study. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team will talk to you about the study and give you this consent form to read. Ask the research team if you have any questions about this form. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

This study is designed to measure the effectiveness of graphic warning labels for cigarettes.

How long will I be in the study?

You will be in this study for a 1 day, ~2-hour lab session. The study is expected to take place for one year.

What am I being asked to do?

You are being asked to complete one visit at the research center. During the visit, you will complete this consent form with a staff member. You will answer a baseline questionnaire, smoke one of your own brand cigarettes outside, look at several warning labels, and answer questionnaires.

At the beginning of the session, you will smoke one of your own cigarettes outside to standardize time to last cigarette smoked. You will answer questionnaires about yourself and your smoking behavior on the computer. You will then look at warning labels on a

computer while having your eye movements recorded. You will answer some follow-up questions after viewing the labels.

What are the possible risks or discomforts?

There are minor risks to this study. Smoking cigarettes has been shown to cause several types of cancer as well as other diseases. The risk of smoking one cigarette during the session does not exceed the risk you encounter as a daily smoker.

Reproductive risks: Smoking can cause serious harm to unborn children or children who are breast-feeding. If you are currently pregnant, it is important that you inform the investigator. You should not be pregnant during this study.

Privacy: As described in this form, procedures are in place to ensure that personal health information is not linked with the results of this research However, this risk is very small, since all information obtained from this study will be kept strictly confidential.

This research may involve risks that are currently unforeseeable.

What if new information becomes available about the study?

During the study, we may find more information that could be important to you, including information that 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 benefit from being in this research study.

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

Your alternative to participating in this study is to not participate.

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

You may choose to join the study, or you may choose not to join the study. Your participation is voluntary.

There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you or would come to you in the future.

Will I be paid for being in this study?

You will be paid $50 compensation for completing the study session successfully; you will be given a Greenphire ClinCard, which is a pre-paid card for the purposes of compensation. Compensation will be loaded onto the ClinCard at the end of the completed session and you will be given the option to receive a text message alert when a payment has been loaded to the ClinCard.

Compensation for task completion depends on you successfully arriving on time for sessions, bringing in your own cigarettes to the session, completing all study instructions including responding to baseline and follow-up questionnaires and eye-tracking session. If you do not complete these tasks, your compensation may be withheld, and you may be withdrawn from the study.

You will be asked to complete a W-9 tax form (includes social security number) at the conclusion of today's session because the University of Pennsylvania is required to report to the Internal Revenue Service (IRS) any total payments for participation in research studies at the University of Pennsylvania that exceed a total of $600.00 in a calendar year. A W-9 will aid the Center and University in tracking and reporting those who participate in multiple projects and may accrue over $600.00 in a calendar year. Further, a social security number is required to register each participant for a Greenphire ClinCard.

Study Payment			
Session	**Visit & Task Compensation**	**Travel Reimbursement**	**Total**
1	$40.00	$10.00	$50.00
STUDY TOTAL			$50.00

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 visits and all the information has been collected. 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 followed the study instructions.
- The PI, the sponsor or the Institutional Review Board (IRB) 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 is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will not interfere with your future care.

How will my personal information be protected during the study?
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 Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

Confidentiality of the data shall be maintained in the following ways:

- Paper-based records will be kept in a secure location (i.e. locked filing cabinet) and only be accessible to personnel involved in the study.
- Computer-based files will only be made accessible to personnel involved in the study through the use of access privileges and passwords.
- Data collected will be stored on a secure server administered by the Penn Medicine Academic Computing Services (PMACS) organization and will be restricted only to those individuals who are authorized to work on the trial.
- Whenever feasible, identifiers will be removed from study-related information (i.e. datasets) and study identification (ID) number will be used primarily.
- Any study communications made by email will use ID numbers only and never include names or any personal information.
- Data Management System (DMS) has safeguards to prevent unauthorized access to study data. In the subject map table, an automatically generated index number is assigned to a subject's study identification number. A linked subject identification table is created to store subject name, address, and telephone contact information. This table uses the automatically generated index number rather than the study identification number. The master subject map and subject identification information are maintained in separate locations.

What may happen to my information collected on this study?

Future Use of Data

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. 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.

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 about your participation 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 not working on the study, contact the University's Office of Regulatory Affairs 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 means that you are permitting the University of Pennsylvania to use your personal health information collected 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. You will be given a copy of this informed consent form.

Name of Subject (Please Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Please Print)	Signature	Date