Document Coversheet

Study Title: Effects of filter ventilation and ventilation information on product use behaviors in cigarette smokers (COMET 2 3.1)

Institution/Site:	Roswell Park Comprehensive Cancer Center
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ROSWELL PARK CANCER INSTITUTE

Title: Effects of Filter Ventilation Information on Product Use Behaviors in Cigarette Smokers (COMET 2 3.1)

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Roswell Park Study Number: I 757820

Consent Form Given to Participant Taking Part in an Investigational/Clinical Research Study

KEY INFORMATION ABOUT THIS RESEARCH STUDY

This is a clinical research study being done by doctors at Roswell Park Comprehensive Cancer Center, Medical University of South Carolina, and Harvard School of Public Health. Clinical research studies include only those participants who choose to take part. Your participation is voluntary. Please take your time to make your decision. Discuss it with your family and with people who are important to you.

We are asking you to take part in this study because you are a current cigarette smoker.

Study Purpose: The purpose of this study is to assess whether messages about ventilation from cigarette filters affects cigarette product appeal among smokers. This project will assess the effect of variation in pack messaging on smokers' rating of product appeal, perceptions of health risk, and changes in cigarette consumption in a 2-week field study.

Study Duration and Number of Participants: It is expected this study will take about two years or will continue until the needed number of participants are enrolled. This study will include about 300 participants nationally. We expect to enroll 100 participants from Roswell Park over two years.

Your participation in this study will be two weeks long.

Research Tests and Procedures: If you take part in this study you will need to have the following *additional* tests as part of your participation:

- Carbon monoxide tests will be done daily, which require you to take a deep inhale, hold your breath for 15 seconds, and then exhale into a monitor. This sample is required for you to take part in this study because the research on the sample is an important part of the study.

Section 3 of this document provides additional information on the tests and procedures involved with this study.

Study Costs: There are no costs to you associated with this study.

Side Effects and Risks: While you take part in this study, you may be at risk for side effects similar to the use of other commercial cigarette products, including those you may smoke yourself. The side effects may be mild, moderate, or severe. The most common side effects of the study drug(s) are: indigestion or heartburn, nausea, vomiting, dizziness, diarrhea, or weakness.

It is very important that you notify your doctor/study investigator right away about any side effects, problems, or unusual experiences you may have while on this study. This will decrease the chance that the side effects continue or become worse. Sometimes there are other resources that we can provide to you to make you more comfortable. If severe side effects do develop, you and your doctor/study investigator may decide it is in your best interest to stop taking part in the study.

Section 6 of this document provides more detailed information on possible side effects and risks.

Potential Benefits: There is no guarantee that being on the study will help you. Future participants may be helped from the results and information gained from this study. Participation in this study may help you understand more about your smoking behaviors. It is hoped that the study will provide information to guide regulation of tobacco and nicotine products.

Other Options: It is your decision to join this study. If you do not join this study, there are no alternative options. If you wish to quit smoking, you should discuss these options with your doctor, a certified tobacco treatment specialist, or contact the New York State QuitLine.

The type of study, the risks, benefits, discomforts, and other important information about this study are discussed below.

ADDITIONAL INFORMATION ABOUT THIS RESEARCH STUDY

It is important that you read and understand the following facts that apply to anyone that takes part in our studies:

a) This study is considered research. It is investigational.
b) Taking part in the study is voluntary.
c) You may withdraw from the study at any time without penalty, loss of any benefits or access to care at Roswell Park to which you are otherwise entitled.
d) If you should decide not to take part in this study, it will not affect your care at Roswell Park now or in the future.
e) You may not be helped from taking part in this study, but we may get information that will help others.
f) If we become aware of important new information that may relate to your willingness to participate in this study we inform you of this information.
g) If you decide to stop being in the study, you should talk with your doctor first about this decision so you are informed whether stopping study participation may have any effects on your health.

1. What is the purpose of this study?

The purpose of this study is to assess if messaging about ventilation from cigarette filters (butts) lowers product enjoyment and cigarette use among smokers. Specifically, this project will measure

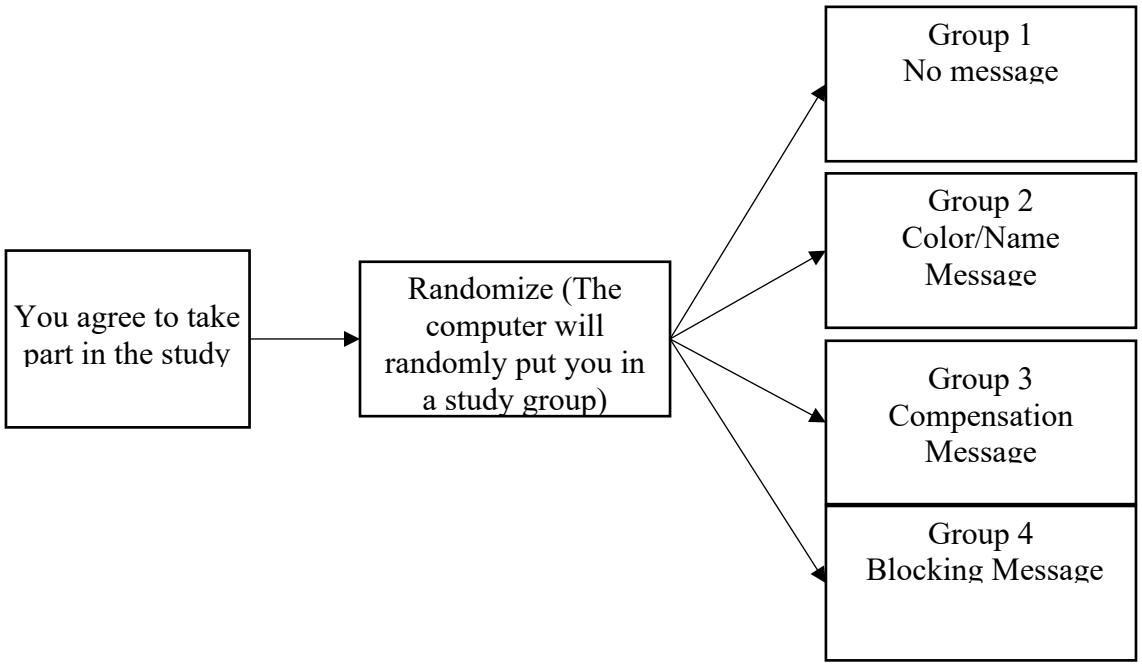
how different messages about the product influence how much someone likes the cigarette, how risky they think the cigarette is, and how it changes cigarette use over 2 weeks. This project is important because it will help regulators, such as the Food and Drug Administration, use data to inform policies on filter ventilation of cigarettes. These policies could eventually help to reduce cigarette use and possibly reduce tobacco-related harms to individuals and the population.

2. What are the study groups?

This study has four study groups that differ by the message on the cigarette pack. Group 1 will receive cigarettes with an unaltered cigarette pack (no message). Group 2 will receive cigarettes with a message about product color/name. Group 3 will receive cigarettes with a message about compensation, or how a smoker may puff differently when cigarettes have vents. Group 4 will receive cigarettes with a message about blocking, or how a smoker may hold cigarettes differently when cigarettes have vents. Participants within each group will have the option between menthol and non-menthol versions of the study cigarettes. You will be expected to smoke *only* the research cigarettes (Marlboro Special Blend or investigational, lab-rolled cigarettes) provided and not your usual brand of cigarettes.

This study involves random (by chance) placement into one of the groups. Neither you nor your doctor can choose the group you will be placed in. Randomization is a process used to place patients in different groups. A statistician will use a computer to assign the groups. By using randomization, the groups will be similar and they can be compared objectively. You will have an equal chance of being placed in either group.

Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.



3. If I take part in this study, what tests and procedures will I have done?

	Data Collection Sessions (Weekly)			Field (Daily for 14 days)
	Video 1	**Video 2**	**Video 3**	**EMA (Ecological Momentary Assessment)**
Tobacco Use Behavior				
Cigarettes per Day	X	X	X	X
Other Tobacco Use	X	X	X	X
Context of Use (e.g., location)				X
Questionnaires				
Message Perceptions (response, health risk, purchase)	X All messages	X Randomly Assigned Message	X Randomly Assigned Message	
Vent Awareness	X	X	X	
Product Evaluation (Duke Sensory, Product Evaluation Scale, Drug Effects, Hedonic Attribute)	X	X	X	X Select Items
Contemplation Ladder (Readiness to quit)	X	X	X	
Withdrawal (MNWS, QSU-B, PANAS)				X Select Items
Attention to Messaging				X
Biomarkers				
Exhaled CO				X
Topography via Filter Analysis				X

This study is a 2-week field study. If you consent to study participation, you will fill out baseline questionnaires today. We will then randomize you to one of the four groups mentioned previously and deliver your study materials. Upon receipt of the study materials, the 2-week field study will begin. In the study, you will be asked to only smoke the research cigarettes provided. Throughout the 2 weeks, you will be asked to videoconference (via Webex, Zoom, or Microsoft Teams) with research staff 3 times (Day 1, Day 7, Day 14 ± 2 days for each). These videoconferencing sessions will take up to 30 minutes and will involve responding to questionnaires about message perceptions, cigarette vent awareness, product evaluation, and interest in quitting smoking.

In addition to the videoconferencing sessions, you will respond to brief questionnaires 5 times every day of the 2-week study. These questionnaires will be sent to you at the same time each day (11am, 1:30pm, 4pm, 6:30pm, and 9pm). These questionnaires are expected to take no more than 5 minutes each, taking up a maximum of 25 minutes daily. These questionnaires will assess your product evaluation, withdrawal symptoms, attention to messaging, and situational factors related to use. Additionally, 1-2 times per day you will collect a breath sample (for carbon monoxide) by breathing into a portable monitor that we will provide for you. You will also be provided with materials to collect all of your used cigarette filters.

When you have completed the study, we will arrange to receive the study materials that you must return (unused study cigarettes, spent cigarette filters).

4. Will I be informed of research results?

If we learn new information from research tests or analyses during this study that may be important to your health or to your disease or condition, we will not be able to share that information with you because this study is unlikely to yield results directly beneficial to you, as the aim of the study is to understand responses to varying levels of cigarette filter ventilation. Thus, findings from this study may not impact your health directly or help you quit smoking.

5. Why would I be taken off the study early?

You may be taken off the study for any of the following reasons:

- Your medical condition changes
- New information becomes known to us that would influence your decision to remain on the study
- You do not follow the study schedule or requirements
    - You are expected to reach 80% EMA compliance daily (≥4 of 5 prompts). Failing to reach 80% compliance for 3 consecutive days will result in a warning. Continued noncompliance will result in study withdrawal. Additionally, failure to respond to all study prompts (0 of 5) for three consecutive days will result in withdrawal.
- You experience unacceptable side effects
- You no longer want to participate

6. What risks and discomforts are involved?

Cigarette Smoking: Cigarette smoking is known to cause cancer and other serious disease. Since we are using commercially available cigarettes, the side effects of the cigarettes used in this study would be like other commercial cigarette products, likely including those you smoke. You could experience an increased risk for mouth sores, gum disease and tooth loss, nausea or stomach aches, vomiting, or high blood pressure. Some people who use cigarettes may experience irritation of the mucosal membranes of the upper respiratory tract (the membranes that line mouth and throat), though this is unlikely to occur.

- Rare but Serious Side Effects: Those that occur in less than 5% of persons who use nicotine products.
    - Mouth irritation
    - Severe sore throat
    - Irregular heartbeat or rapid heartbeat
- More common but less Serious Side Effects: Those that occur in less than 10-30% of persons who use nicotine products.
    - Indigestion or heartburn
    - Nausea, vomiting, dizziness, diarrhea, or weakness

Survey: The study will involve your provision of responses to questions about tobacco and nicotine products. The chance of risk or discomfort is ‘none to minimal’. In the unlikely event of distress caused by participation in the study, Dr. O’Connor will be available to identify psychological resources for you.

Carbon monoxide testing: There is none to minimal risk associated with exhaling air into a monitor to measure your carbon monoxide levels. No samples are retained after the reading.

7. Reproductive risks

The cigarettes in this study may be harmful to unborn babies and to breastfed children. If you are pregnant or suspect you may be pregnant, or are breastfeeding, you should not take part in this study.

When you sign this consent form, to the best of your knowledge, you are not pregnant and do not plan to become pregnant while taking part in this study. Should you become pregnant during this study, you need to immediately tell your study doctor and obstetrician. If you wish you may request a referral for counseling or ask about counseling (such as genetic counselor, social worker, or psychologist.) to discuss this further.

8. What are my responsibilities in this study?

If you choose to take part in this study, you will need to:

- Keep your study appointments.
- Use only the research cigarettes provided to you. Keep study cigarettes out of the reach of children and do not share them with any other person.
- Respond to daily questionnaires about tobacco use.
- Return materials (e.g., unused cigarettes, used cigarette butts) at the end of study.
- Please refrain from using cannabis/marijuana/THC during the study.
- Tell your doctor about:
    - All medications and supplements you are taking
    - Any side effects
    - Any doctors' visits or hospital stays outside of this study
    - If you have been or are currently in another research study.

9. What happens if I am injured as a result of this study?

If you believe you have been injured as a direct result of your participation in this research study, notify the Roswell Park Patient Advocate at (716) 845-1365 or the Study Doctor at (716) 845-4517.

Medical diagnosis and treatment for the injury will be offered, and a determination will be made regarding appropriate billing for the diagnosis and treatment of the injury. A financial counselor can be reached at 716-845-3161 to provide an explanation of coverage and to answer questions you may have regarding study related billing.

You do not give up any legal rights by signing this form. You are not prevented from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

10. Will I be paid for joining this study?

You will receive the following payment for participating in this study: You will be paid $50.00 for each of three videoconference sessions (total $150). Payment will be in the form of a gift code (e.g., Amazon, Target). Additionally, you can earn up to $10 for each day of 100% EMA

compliance (5 of 5 messages for up to 14 days, total $140), which will be paid by check at the end of the study. Total possible compensation is $290.

It is possible that this research project may result in developing treatments, devices, new drugs, or procedures that could be used for commercial profit by the sponsor or other entities. If this happens, you understand that you will not receive any financial payment or share in any commercial profit for the use of your information and biospecimens (such as blood or tissue samples) collected as part of this research.

11. Where can I find more information?

You may call the NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

For accurate cancer information including Physician Data Query (PDQ), visit https://www.cancer.gov.

If you are interested in stopping smoking, you can call the New York State Smokers QuitLine on 1-866-697-8487 (1-866-NY-QUITS), or visit www.nysmokefree.com

12. Who do I contact with questions?

You are free to ask questions at any time about this study and to ask for more information from the doctor identified on this document. If you have any questions, concerns or complaints about this study, you should contact the Richard O'Connor, Ph.D., at (716) 845-4517 at Roswell Park. In case of an emergency after regular hospital hours, you should telephone (716) 845-2300 and ask for the doctor on call.

If you have questions about your rights as a research subject or you feel you have been injured as a result of your participation in this research study, you can call the Roswell Park Patient Advocate (Support) Office at (716) 845-1365. You should also feel free to contact the Patient Advocate Office at any time while considering participation, during participation or once your participation is complete. This office is unaffiliated with any specific research study. They can help you obtain additional information regarding your research participation and your rights as a research subject or how to proceed should you feel you have been injured as a result of your participation. They are available to discuss any problems, concerns, questions or input you may have.

It may be necessary to contact you at a future date regarding new information about this research study. For this reason, we ask that you notify the Patient Access office at 716-845-1049 or stop at the Registration Desk in the Lobby of Roswell Park to update us of any change in your address.

13. Conflict of Interest Statement

The National Institutes of Health (NIH) pays for the conduct of this study, including part of the Dr. O'Connor's salary.

- Any questions regarding financial conflict issues can be directed to your doctor or to Donald J. Handley, MBA, MS, Executive Director Research Subject Protections, who can be reached at 845-3455.
- This disclosure is made so that you can decide if this relationship will affect your willingness to participate in this study

CONFIDENTIALITY AND USE OF HEALTH INFORMATION

What about confidentiality?

Your privacy is very important to us and the researchers will make every effort to protect it. Your information collected in this study may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect the study records and your information. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration and the National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.

All data related to the study will be maintained on password-protected, limited access computer servers behind Roswell Park's firewall. While this is a high level of protection, there is a small risk of data breach. To protect against this, any files containing your identifying information will be kept separate from any files containing your study data, with only an ID number linking them. Only the PI and his staff will have access to this link. All data analyses will involve de-identified data to protect the confidentiality of the data and your privacy. However, it is not anonymous – we must maintain certain information identifying you, such as your name, address, telephone number, and date of birth, for recordkeeping purposes. This information is used for study logistic purposes only – for example, to make sure the same person does not complete the study multiple times, and to communicate with you about study appointments.

Your information or biospecimens (such as blood or tissue samples) collected as part of the research, even if all information that does or can identify you is removed, will not be used or distributed for future research studies.

Certificate of Confidentiality

As an additional measure to protect your privacy, a Certificate of Confidentiality has been issued from the United States Government, National Institutes of Health, for this study. With this Certificate, the investigators and institutions involved in this study cannot be forced to disclose

information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding. We will use this Certificate to resist any demands for information that would identify you, with the following exceptions:

- The Certificate cannot be used to resist a request for your information from the United States Government when the information is to be used for auditing or evaluation of federally funded projects or for information that must be disclosed to meet the requirements of the Food and Drug Administration (FDA).
- State law requires we report cases of diseases that spread easily, or abusive behavior (toward a child, a partner, or an elderly person), and people who say they are going to hurt themselves or someone else.
- The Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or involvement in this research. Also, if you have given written consent to an insurer, employer, or other person to receive research information, then we may not use the Certificate to withhold the information.

OPTIONAL RESEARCH

This part of the consent form is about optional studies that you can choose to take part in. We may recruit cigarette smokers for future studies and may be interested in contacting you to participate in these future studies. The research from these studies may help other people with cancer or other diseases in the future. You can still take part in the main study even if you say "no" to this optional research.

I agree that someone may contact me in the future to ask me to take part in more research.

PLEASE CHECK ONE BOX

YES ☐ **NO** ☐

Statement of Investigator/Person Conducting the Informed Consent Discussion:

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained and that any questions about this information have been answered. A signed copy of this consent will be given to the participant.

SIGNATURE_____ **DATE**_____ **TIME**_____

PRINTED NAME _____

Participant's Statement of Consent:

By signing below, you agree that:

- You have been told of the reasons for this study.
- You have had the study explained to you.
- You have had all of your questions answered, including those about areas you did not understand, to your satisfaction.
- You have carefully read this consent form and will receive a signed copy of this form.
- You do **not** waive any **legal** rights you have under federal or state laws and regulations.
- You willingly give your consent to voluntarily join in this research study.

Participant:

SIGNATURE_____ **DATE**_____ **TIME**_____

PRINTED NAME _____

Witness Signature is needed in the following circumstances – check below:

☐ Not Applicable
☐ The person consenting cannot write – mark must be made as appropriate.
☐ The person consenting cannot read - consent has been read to him/her.
☐ The person consenting cannot understand English and the consent has been verbally interpreted.

(The witness should be fluent in both English and the language of the person consenting.)

Witness Statement:

The person consenting has signed this document in my presence.

SIGNATURE_____**DATE**_____ **TIME**_____

PRINTED NAME _____

RELATIONSHIP TO PARTICIPANT_____

CONSENT HANDLING
Original to CRA-Regulatory with Race/ Ethnicity if applicable
Copy to:

- Patient
- CRS registration
- Medical Records