

INFORMED CONSENT TO TAKE PART IN A QUALITATIVE STUDY to Develop PARE Cigarettes Consumer Messaging

Why do I need to read this form?

This form explains:

- Why you are here today and what you will be doing
- Why we are conducting this research
- Any risks associated with your participation
- Your rights and responsibilities as a participant

Please review this form carefully and ask all questions of the investigators before you sign below. When you believe you understand the purpose of this study and you agree to take part, please sign this consent form.

What is this study about?

M/A/R/C® Research is conducting research with current smokers to develop product messages for modified risk tobacco products (“MRTP’s”). MRTPs are new tobacco products for existing smokers. This research is about various tobacco products including a new MRTP product called PARE Cigarettes.

The study is designed to understand:

- If statements created about PARE Cigarettes are clear;
- If current smokers intend to use PARE Cigarettes; and
- What current smokers believe are the risks in using PARE Cigarettes.

What will happen today?

Today you will be part of a 1 hour and 15-minute group discussion with up to 6 participants, including you. In this group, you will discuss various tobacco products. You will not be asked to smoke or otherwise try any tobacco products, including PARE Cigarettes, and no promotion of any tobacco brand or product will occur.

The discussion will be audio taped (no videotaping). Access to the recording, your personal information and any thoughts or opinions you share will be held in strict confidence.

You will be compensated USD \$100 for participating in the group discussion.

Some sensitive information (“Confidential Information”) about the product may be shared during the group discussion. Any confidential information that is shared may not be disclosed to anyone outside of this group discussion.

Are there any risks to me in participating in this research?

In the discussion today, other people will hear your opinions and any other information you share about yourself. We will only use your first name during the group and your input will be confidential.

Your input will be analyzed as part of a broader study where your specific opinions will be anonymous relative to hundreds of other participants.

Using tobacco products is known to cause disease and early death. Talking about tobacco products may cause you to crave tobacco. What is learned may inform messaging for PARE Cigarettes. There is no direct benefit to you for taking part in this study, outside of the incentive paid for your time.

(b)(6) – M/A/R/C® Research

STUDY TITLE: Qualitative Study to Develop PARE Cigarettes Consumer Messaging

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Will I be paid for being in this study?

You will be paid USD \$100 for your participation in this study.

Do I have to participate in this study?

It is your decision to take part in this research study. Participation is voluntary and you may change your mind and stop at any time with no penalty or loss of benefits, or may request to exclude your input from the final results.

The investigator or the research sponsor may also stop the research at any time.

What if I have questions?

If you have questions about this study, please contact the study staff at **M/A/R/C® Research**.

STUDY TITLE:	Qualitative Study to Develop PARE Cigarettes Consumer Messaging
PRINCIPAL INVESTIGATOR:	(b)(6) – M/A/R/C® Research
TELEPHONE:	(800) 884-6272
ADDRESS:	7850 North Belt Line Road Irving, TX 75063
SPONSOR:	22nd Century Group, Inc.

By signing the Informed Consent Form & Confidentiality Declaration, I agree that I have been provided with a copy of this form and that I have read and understand the purposes of this research, what will happen today, the risks associated with the research, what I will be paid for my participation and who to contact if I should have questions.

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INFORMED CONSENT FORM & CONFIDENTIALITY DECLARATION

VOLUNTEER'S STATEMENT:

I agree to participate in this research discussion group about Modified Risk Tobacco Products ("MRTPs"). MRTPs are new tobacco products for existing smokers. I have been provided copies of the **Informed Consent to Take Part in a Qualitative Study** and **My Research Responsibilities & Risks of Cigarette Smoking/MRTPs** documents.

By signing below, I indicate that I have read, understood and been provided a copy of these disclosure documents.

I understand and agree that:

- I am of legal age in my state to smoke cigarettes
- I have been informed of the nature of this Research and will participate in a group discussion today lasting approximately 1 hour and 15-minutes for which I will be compensated USD \$100
- I may address any current or future questions about this research to **M/A/R/C® Research**
- Any questions that I asked before signing this have been answered to my satisfaction
- My participation is voluntary; I may stop participating at any time
- All Confidential Information (visual, oral or written) presented during the Research will remain confidential for a period of 10 years and I will not share any Confidential Information with any third parties (by social media sites, or to friends, relatives or family), directly or indirectly, unless required to do so by law
- I will hand over all electronic devices for safekeeping to **M/A/R/C® Research** while I participate in the discussion to help ensure product confidentiality
- All information I share today may be retained and used by **M/A/R/C® Research** or **22nd Century Group, Inc.** for the purposes of this research but it will not be used for any other purpose

I have read and understand all information, written or verbal, that I have been provided. By signing this form, I do not waive any of my legal rights. On signing below, I will be provided with a copy of this Informed Consent Form & Confidentiality Declaration. This form will be stored for an indefinite period of time by **M/A/R/C® Research**.

Signature of Study Participant

Date

Printed Name of Study Participant

FOR USE BY AGENCY ONLY

Signature of Person Obtaining Consent

Date

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My Research Responsibilities & Risks of Cigarette Smoking/MRTPs

My Research Responsibilities

- The purpose of this research is to understand current smoker's reactions to product messages.
- I am responsible for asking questions that I may have about the research, providing any thoughts or opinions I may have during the research and actively participating in the discussion.
- My participation is voluntary and I may leave this discussion at any time if I no longer wish to participate.
- I am prohibited from revealing any confidential information (written, verbal, visual) that is presented during this research. This may include the design, images, messages, statements or any other product communications.
- All information I receive during this research is considered confidential and may not be disclosed by me to any third party via written, verbal or visual means for up to 10 years.
- I am also prohibited from keeping any materials presented during the group discussion. All materials presented must be returned to the M/A/R/C® Research staff before I leave the facility today.

Risks of Cigarette Smoking/MRTPs

- Smoking causes serious and fatal diseases such as lung cancer, heart disease and emphysema in smokers. Smokers are far more likely to develop serious diseases like lung cancer than non-smokers.
- Cigarette smoking during pregnancy is associated with increased risk of pregnancy complications, spontaneous abortion, low birth weight infants and stillbirth.
- Cigarette smoking is addictive. It can be very difficult to quit smoking, but this should not deter adult smokers who want to quit from trying to do so.
- There is no such thing as a safe cigarette. Using MRTPs has not been shown to be safer than smoking conventional cigarettes and in addition MRTPs should not be viewed as an alternative to quitting smoking.
- Anything communicated during this research is not in any way intended to promote smoking, a particular MRTP or MRTPs in general.

By signing the Informed Consent Form & Confidentiality Declaration, I agree that I have been provided with a copy of this form and that I have read and understand my responsibilities and the risks associated with cigarette smoking / MRTPs.