

**INFORMED CONSENT AUTHORIZATION TO PARTICIPATE
IN A RESEARCH STUDY**

Title: (Protocol #: CSD0904) Post-Market Surveillance of Tobacco Products: A Multicenter Clinical Trial of Natural Adopters of Cigarettes, Moist Snuff, Camel SNUS, and Dual Use

Principal Investigator: E. David Pampe, M.D.

Site of Investigation: MetaClin Research, Inc.
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Austin, Texas 78749
512-732-2444

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Unit D, Suite 102
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24 hour Telephone #: 512-732-2444 ext.2

Sponsor: R.J. Reynolds Tobacco Company

Participant's Name: _____

You are invited to participate in a research study. Before you give your consent to be a research participant, we want you to read the following and ask as many questions as necessary to be sure that you understand the risks and what your participation will involve.

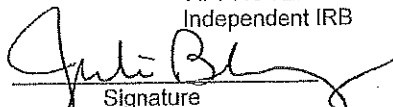
The Study is being sponsored by R.J. Reynolds Tobacco Company (RJR) and the Study Doctor is being paid by RJR to conduct this study. However, the Study Doctor will not receive any financial benefit based on the outcome or results of this study.

NATURE AND PURPOSE OF THE STUDY

The main purpose of this study is to collect biological data from consumers of tobacco products for RJR's research purposes. These data will be obtained by collecting and analyzing samples of blood, urine, cells from the mouth, and saliva. These data will be useful in determining levels of tobacco exposure in tobacco consumers and in assessing the effects of tobacco products on consumers.

Another purpose of this study is to assess the effects of tobacco use on your physical capacity by performing a breathing test before and after a walking test.

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RJR wants to evaluate and compare these data and physical assessments in several groups of people:

- 1) those that normally consume only one type of tobacco product (such as cigarettes, moist snuff, or Camel SNUS),
- 2) those who consume both cigarettes and Camel SNUS or both cigarettes and moist snuff, and
- 3) those who do not consume any tobacco products.

Your perceptions about your own health status will also be asked on several questionnaires.

There are no investigational products being consumed in this study. The device used to measure the amount of carbon monoxide in your breath is investigational and therefore has not been cleared by the FDA.

This study is for research purposes only and is not intended to treat any medical condition.

RESEARCH PARTICIPANT SELECTION

You are being invited to participate in this research study because you are a male or female who is at least 19 years of age and in generally good health. Research participants must also meet certain other criteria to participate in this study. Research participants will be grouped by the amount and type of tobacco products used. You will be assigned to one of the following six groups below, based on your self-report of the type of tobacco product(s) you normally use:

- Moist snuff consumers (Approximately 50 participants)
- Camel SNUS consumers (Approximately 50 participants)
- Consumers of both Camel SNUS and cigarettes (Approximately 50 participants)
- Consumers of both moist snuff and cigarettes (Approximately 50 participants)
- Cigarette smokers (Approximately 60 participants)
- Non-tobacco consumers (Approximately 60 participants)

Females must not be pregnant, breastfeeding, or planning on becoming pregnant during their participation in this study.

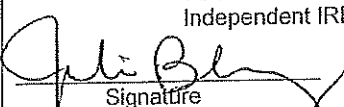
It is important that you answer all of the screening questions completely. You must provide information on all past and present diseases, allergies and all medications that you are taking, including prescription and non-prescription medications. You must be honest about your current state of health and your current tobacco use.

Approximately 320 research participants will be enrolled in this multi-site research study.

STUDY DURATION

The length of your participation in this study will be approximately 5½ weeks or less, depending upon study procedures required for your group. This includes initial screening

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procedures which may be completed over a period of several days, one pre-enrollment outpatient visit, and one clinic confinement period. The confinement period requires one stay of 2 days and 1 night. Your participation in this study will be over once you complete the overnight confinement stay at the clinic.

STUDY DESIGN

If you are a tobacco consumer, you will continue to use your current brand and type of tobacco products during the duration of the study. If you do not consume any type of tobacco products, you will be asked to continue to not use any form of tobacco.

Prior to checking in for the clinic confinement, all research participants will return to the clinic for an outpatient visit to perform a breathing test and pick up a special urine collection kit. During this visit, tobacco consumers will also pick up collection kits and instructions for collecting used cigarette butts and/or snus pouches or snuff containers. You will bring the collection kits with you when you check into the clinic on the morning of Day 1 for your overnight visit.

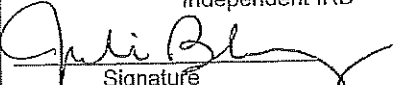
All research participants will come and stay overnight at the clinic beginning on Day 1. During this visit, blood, urine, and saliva samples will be collected. A walking test and several breathing tests will be performed, and you will be asked to complete some questionnaires. The questionnaires may take between 15 and 30 minutes to complete.

SCREENING

Depending on your study group, you will come to the clinic for an initial screening visit approximately two to four weeks prior to your overnight visit. Prior to any procedures being performed, you will be asked to sign this informed consent form. During the initial screening visit, you will have the following procedures performed:

- Your demographics (e.g., age and gender) will be collected.
- Your medical and medication history will be reviewed.
- Your history of tobacco use will be assessed, and if you are a tobacco consumer, your usual brand of tobacco product(s) will be documented.
- Your height, weight and vital signs (blood pressure, pulse, oxygen level and temperature) will be measured.
- You will have a physical exam, including an exam of your mouth.
- You will have an electrocardiogram (ECG) performed, which uses adhesive sensors on the skin to measure and create a record of your heart rhythm.
- Your blood and urine will be collected for routine clinical laboratory evaluation.
- Your blood will be screened for hepatitis and HIV.
- You will have a urine screening test for drugs of abuse. This test must be negative for you to continue in the study.
- You will have a breath alcohol test performed to ensure that you are not under the influence of alcohol. This test must be negative for you to continue in the study.
- You will have a urine screening test for tobacco use.

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- If you are a female, you will have a urine pregnancy test to be sure you are not pregnant. You will also be asked whether you are currently breast feeding a baby.
- You will also be asked to breathe into a machine that measures the level of carbon monoxide in your breath.

You will be notified of any positive test results for hepatitis and/or HIV, and such results may also be reported to the local health agency in accordance to local and state laws. In addition, based on state law or clinic policy, you may be asked to sign a separate HIV and Hepatitis consent form.

After reviewing the results of the screening tests and other assessments, the Study Doctor will decide if you can be in the study. You must meet all of the study conditions. You will be told of any study restrictions.

If you qualify for the study, there is a small chance that you cannot be enrolled in the study within 35 days of your initial screening visit. If this occurs, study staff will contact you and invite you to complete a second screening. If you agree to be re-screened, you will be compensated for this extra visit.

STUDY PROCEDURES

If the Study Doctor has decided that you meet the study criteria, you will be contacted by phone to schedule further visits. If you are still willing to participate in this study, you will be asked to return to the clinic to pick up a special urine collection kit and, if you are a tobacco consumer, special kits and instructions for collecting used tobacco products prior to Day 1. While at this visit, you be asked to complete a breathing test called spirometry. This test requires you to take a deep breath and then exhale into a machine as hard as possible, for as long as possible. You will be asked to do this about three times, but not more than eight.

If the Study Doctor believes you are not able to safely complete this test, you will not be allowed to continue to participate in the study.

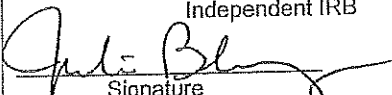
Tobacco Product Collection Kit (*Tobacco Consumers Only*)

You will be asked to continue your normal rate of tobacco product usage, using your usual brand of tobacco product(s).

Camel SNUS Consumers: You will be asked to collect all your used Camel SNUS pouches for 7 consecutive days. The collection can begin within 14 days of your scheduled check-in on Day 1, but it must be completed prior to Day 1. You will be provided 7 separate labeled jars (one for each day), in which you will place all your used snus pouches. You must store the jars in the freezer until you return to the clinic for check-in on Day 1. You will also be asked to record each day on a diary any snus pouches that you forgot to place in the jars. You will bring your collection jars and diary to the clinic on Day 1.

Cigarette Smokers: You will be asked to collect all your used cigarette butts in a specially designed collection kit for only the 24 hours prior to check-in on Day 1. You will bring this

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collection kit to the clinic on Day 1. You will be asked to record on a diary any cigarette butts that you forgot to place in the collection kit.

Moist Snuff Consumers: You will not be collecting your used moist snuff. However, 24 hours prior to check-in on Day 1, you will start with a new, unopened container of moist snuff (labeled Container #1) and bring the remainder of Container #1 to the clinic on Day 1.

Consumers of both Camel SNUS and Cigarettes or both Moist Snuff and Cigarettes: You will follow the instructions in two of the above categories collecting the type of tobacco products that you are currently using.

Urine Collection Kit (All Participants)

You will be given a special urine container by the study staff. You will record on the container label the time of your first urine void of the morning on Day 1. You will NOT collect this void. However, in case you need to urinate a second time before you reach the clinic to check-in, you will collect this second urine void in the special urine container and keep it cool in the kit provided. You do not need to record the time of this second void.

Confinement Visit Day 1

The Day 1 visit will occur no later than 35 days after your initial screening visit, if the Study Doctor decides you can continue after you have completed the pre-enrollment procedures required for your group.

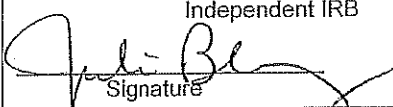
You will come to the clinic between 6:00 and 8:00 in the morning to begin your 24-hour overnight visit. Whether or not you collected any urine during the morning prior to coming to the clinic, you will bring this entire collection kit with you to the clinic.

After checking in, you will have the following procedures performed:

- You will turn in the special urine collection kit.
- You will have a urine screening test for drugs of abuse. This test must be negative for you to continue in the study.
- You will have a breath alcohol test performed. This must be negative for you to continue in the study.
- You will have a urine screening test for tobacco use.
- If you are a female, you will have a urine pregnancy test to be sure you are not pregnant.
- You will have the carbon monoxide levels in your breath measured.
- You will begin to collect all of your urine for the next 24 hours in a special container provided by the study site.

If you are a tobacco consumer, you will turn in your used tobacco product collection kit(s) and/or your moist snuff containers. You will be asked to bring enough of your usual brand of tobacco product(s) to use during the entire time you will be at the clinic (Day 1 and the morning of Day 2). The study staff will confirm that you are still using the same brand of

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tobacco products that you reported at screening. The study staff will keep your tobacco products and give them to you as you would like them, except during a series of study procedures you will perform after lunch on Day 1. These study procedures will take approximately 1 to 1½ hours to complete. After completion of these study procedures, the study staff will again give you your tobacco products as you would like them up until 10:00 PM on Day 1. You will be asked to collect all used cigarette butts, used snus pouches, and moist snuff containers during your stay at the clinic.

You will have the following procedures performed during this visit:

- You will have your vital signs (blood pressure, pulse, oxygen level, temperature) measured.
- You will complete several questionnaires:
 - Regarding your tobacco use habits.
 - Regarding your health, how you feel, and how well you are able to do your usual activities.
 - Regarding cough, phlegm (mucus), wheezing, breathlessness, chest colds/illnesses, past illnesses, occupational history, tobacco smoking, and family history.
- If you are a tobacco consumer: At least 45 minutes after lunch, you will not be allowed to use any tobacco products for a 30 minute period. At the end of this 30 minutes, you will be asked to use your usual tobacco product. Thirty (30) minutes after this product use, you will provide a blood sample, and shortly after, you will have your carbon monoxide levels measured.
- If you are not a tobacco consumer: At least 75 minutes after lunch, you will provide a blood sample, and shortly after, you will have your carbon monoxide levels measured.
- You will be asked to complete a breathing test (spirometry) by taking a deep breath and then exhaling into a machine as hard as possible, for as long as possible. You will be asked to do this at least three times but not more than eight times.
- You will then be asked to complete a 6 minute walk test. The object of this test is to walk as far as possible for 6 minutes. You will walk back and forth in a specific hallway. Six minutes is a long time to walk, so you may become tired. You may get out of breath or become exhausted. You are allowed to slow down, to stop, and to rest as necessary. You may lean against the wall while resting, but resume walking as soon as you are able. You will be walking back and forth around cones. You should go around the cones and continue back the other way without pausing. The study staff will demonstrate the correct procedures for the test.
- Following the 6 minute walk test, you will be asked to rate your level of breathlessness and fatigue.
- You will complete another breathing (spirometry) test.

Periodically during the study, you will be asked how you are feeling. You will remain at the clinic overnight. You will not be permitted to use any tobacco products or eat or drink anything except water after 10:00 PM.

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Confinement Visit Day 2

In the morning, you will complete your 24 hour urine collection. A blood sample and two saliva samples will also be collected.

One sample will be collected by simply spitting into a special tube 2 or 3 times until enough oral fluid ("spit") has been collected. The staff will coach you on how to do this.

The other sample will be easily collected using the swish and spit method. This procedure is safe and painless. It collects the cells from the inner lining of the cheeks. These are called buccal cells. These cells are routinely shed and replaced by new cells. As the old cells die, they build up in the saliva in the mouth. These are the steps for the "swish and spit" method:

- In the evening of Day 1, before you go to bed, you will brush your teeth.
- The morning of Day 2, you cannot brush your teeth.
- You will rinse your mouth with Scope™ mouthwash for about 15 seconds and spit the mouthwash out.
- You will again rinse your mouth with Scope™ mouthwash for about 15 seconds and spit the mouthwash out.
- Then, you will rinse your mouth with water for about 30 seconds and spit the water out to wash off the Scope™.
- Next, you will gently massage the outside of your cheeks while swishing with water for 30 seconds.
- You will then spit this water into a collection tube.

You will be offered breakfast. Once you complete your 24-hour in-clinic tobacco usage collection all of your tobacco products will be returned to you.

After adequate evaluation by the study staff and with permission of the Study Doctor, you will be discharged from the research clinic, and your participation in this study will be complete.

If necessary, the study doctor may require that you stay longer for observation in the research unit.

Meals

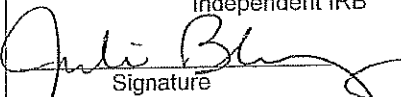
Standardized meals and snacks will be served at regular times during your stay at the clinic, except when fasting is required or otherwise noted. You will not be allowed to bring snacks or other food items or drinks with you during your stay at the clinic.

Blood Sampling

Blood samples will be taken approximately 3 times throughout the course of the study. Approximately 130 mL of blood, about 9 tablespoons, will be drawn during the study. It is possible that more than one needle stick may be necessary during any or all of the blood draws to find a good vein from which to draw the blood.

Additional blood samples may be drawn during the study if the study doctor considers it necessary for monitoring your health.

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For comparison, a standard blood donation at a blood collection center, once in any 56-day period is about 500 ml (approximately 2 cups) of blood.

Restrictions and Research Participant Responsibilities

As a research participant you will be asked to complete all study procedures for this study, come to the research clinic for all of your scheduled visits, follow the instructions listed in this informed consent form, and notify the Study Doctor if any information regarding your health or availability to participate in this study changes.

You will not be permitted to use any tobacco products for approximately 1 to 1½ hours after lunch on Day 1.

You will not be permitted to use any tobacco products after 10:00 PM on Day 1 through collection of all your laboratory samples on Day 2.

You will not be permitted to consume any food or drink (except water) after 10:00 PM on Day 1 through collection of all your laboratory samples on Day 2.

You must avoid vigorous exercise 2 hours prior to the 6 minute walk test.

RISKS AND DISCOMFORTS

Tobacco Consumers

There may be risks to you if you participate in this study. If you are a tobacco consumer, the risks associated with the use of your normal type of tobacco product will remain the same. According to the Surgeon General and other public health authorities, all tobacco products carry significant risks.


Tobacco-burning cigarettes have been required by law to carry one of four warning labels. The four warning labels for these products are:

- SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy.
- SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.
- SURGEON GENERAL'S WARNING: Smoking by Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight.
- SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

Starting in 2012, cigarettes will be required by law to carry the following Warnings:

- WARNING: Cigarettes are addictive.
- WARNING: Tobacco smoke can harm your children.
- WARNING: Cigarettes cause fatal lung disease.
- WARNING: Cigarettes cause cancer.
- WARNING: Cigarettes cause strokes and heart disease.
- WARNING: Smoking during pregnancy can harm your baby.

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- WARNING: Smoking can kill you.
- WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
- WARNING: Quitting smoking now greatly reduces serious risks to your health.

Camel SNUS, moist snuff and other oral smokeless tobacco products have been required to carry one of three warning labels:

- WARNING: This product may cause mouth cancer.
- WARNING: This product may cause gum disease and tooth loss.
- WARNING: This product is not a safe alternative to cigarettes.

Starting in 2010, smokeless tobacco products will be required by law to carry the following Warnings:

- WARNING: This product can cause mouth cancer.
- WARNING: This product can cause gum disease and tooth loss.
- WARNING: This product is not a safe alternative to cigarettes.
- WARNING: Smokeless tobacco is addictive.

STUDY PROCEDURE RISKS

Blood Samples

During the collection of blood samples, you may experience pain and/or bruising at the insertion site of the needle. Although rare, blood clots may form and infections may occur. Lightheadedness and/or fainting may also occur during or shortly after the blood draw.

Breath Test (Spirometry)

This procedure measures how much air your lungs can hold and how air moves into and out of your lungs. You will have a clip placed on your nose and be instructed to take a deep breath and blow through a clean disposable mouthpiece into a machine, exhaling as hard as possible, for as long as possible.

Because spirometry is a non-invasive procedure, it is safe and painless for most individuals. However, common complications may include:

- Dizziness, faintness or light-headedness due to hyperventilation
- Asthmatic episode precipitated by the deep breathing maneuvers.

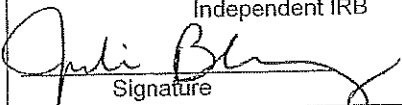
In rare cases, the following may be experienced:

- Chest pain
- Uncontrolled coughing
- Intracranial hypertension (high blood pressure in the brain)
- Pneumothorax (a partial or total collapse of the lung)
- Bronchospasm (tightening of the muscles that surround the airways).

6 Minute Walk Test

During the 6 minute walk test, you may feel tired, exhausted, out of breath, and sweaty. You can lean against the wall if you would like; then continue walking whenever you feel

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able. If you experience any chest pain or problems breathing, or any other pain or discomfort, you should tell the study staff immediately.

Completion of Questionnaires & Surveys

There are no known risks associated with completing the questionnaires and surveys in this study. You may find certain questions uncomfortable. Completion of the questionnaires and surveys are required as part of your study participation.

UNKNOWN/UNFORESEEABLE RISKS

To tobacco consumers, in addition to the risks listed above, there may be other unknown, infrequent, or unforeseeable risks associated with the use of tobacco products.

You will be informed in a timely manner both verbally and in writing of any new information, findings or changes to the way the research will be performed that might influence your willingness to continue your participation in this study.

PREGNANCY RISKS

The Surgeon General warns that cigarette smoking by pregnant women may harm the unborn baby, complicate pregnancy and may result in premature birth, and low birth weight. Women who are pregnant, planning to become pregnant or are breast feeding cannot participate in this study.

BENEFITS

It is understood that participation in this study is purely for RJR's research purposes, and no benefits to you are expected or promised.

COST

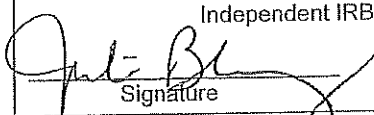
You will be asked to purchase enough of your usual brand of tobacco products for use in this study. Tobacco products will not be paid for or provided by the study clinic or Sponsor. There are no other costs to you for participating in this research study. The study Sponsor pays for all other additional study costs.

PAYMENT

If you are a tobacco consumer, you may be paid up to a total of \$425.00 for your participation in this study. If you do not consume tobacco products, you may be paid up to a total of \$325.00 for your participation in this study. If you do not complete the entire study, you will be paid for the visits that you complete based on the following payment schedule:

Payment Breakdown	Tobacco Consumers	Non-Tobacco Consumers
Initial Screening Visit	\$50.00	\$50.00
Pre-Enrollment Outpatient Visit (Occurs prior to Clinic Confinement)	\$50.00	\$50.00
7-Day Pre-Clinic Product Collection (Tobacco Consumers only)	\$50.00	N/A

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1-Day Pre-Clinic Product Collection (Tobacco Consumers only)	\$50.00	N/A
Day 1 (Beginning of Clinic Confinement)	\$150.00	\$150.00
Day 2 (End of Clinic Confinement)	\$75.00	\$75.00
Total	\$425.00	\$325.00

If you qualify for the study but cannot be enrolled within 35 days of your initial screening visit, you may be invited to re-screen for the study. If you choose to be re-screened, you will be compensated \$50.00 for this additional visit.

You will be paid 2 weeks after completion of your last visit for your participation.

ALTERNATIVE

Since this study is not intended to provide participants any therapeutic or other health-related benefit, you have the alternative to not participate in this study.

RIGHT TO WITHDRAW OR REMOVAL FROM STUDY

Participation in this research study is voluntary. You are free to withdraw from this study at any time for any reason. You agree to inform the Study Doctor immediately if you intend to withdraw for any reason, but you do not have to state your reason if you don't want to. If you withdraw because you intend to quit using tobacco, the Study Doctor will refer you to appropriate resources to help you stop smoking or using tobacco. However, you will not be allowed to continue your participation in the study.

To terminate your participation in this study, you must contact the Study Doctor at the phone number listed on Page 1 of this informed consent form. Your decision to participate in this study or to withdraw from this study will not influence the availability of your future medical care and will involve no penalty or loss of benefits to which you are otherwise entitled.

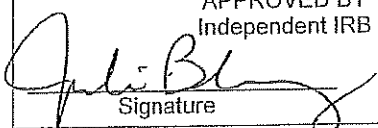
You agree that the Study Doctor in charge of the study can remove you from this study without your consent for any reason, including, but not limited to:

- a. A change in your qualification status that makes you no longer eligible for participation according to the study requirements or that which may affect your safety.
- b. Your failure to follow the instructions of the Study Doctor or clinic staff.
- c. If the study is stopped by the Sponsor and/or doctors participating in the study prior to its completion.

Should you decide to withdraw from participation in the study or if the Study Doctor decides to remove you from the study for any reason, you will be asked to complete some final safety procedures, such as rechecking your blood pressure, pulse, and temperature.

OFFER TO ANSWER ANY QUESTIONS ABOUT THIS STUDY

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If you have any questions, concerns, or complaints during this study, or if you think you may have experienced a research-related injury, you should contact E. David Pampe, M.D, at (512) 732-2444.

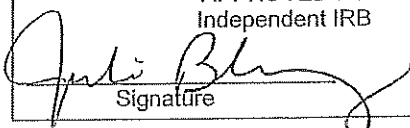
If you have any questions regarding your rights as a research participant, please contact the Independent Investigational Review Board, Inc. at toll free 1-(877) 888-iirb (4472) during regular working hours. You can also contact the Independent Investigational Review Board, Inc. if you would like to report problems in a research study, express concerns, ask questions, request information, or provide input. The Independent Investigational Review Board is a committee established for the purpose of protecting the rights of participants in a research study. For more information about your rights and role as a research participant you can visit the Research Participant section of the IIRB, Inc. website at www.iirb.com.

USE AND DISCLOSURE OF MEDICAL INFORMATION

As part of this study, the Study Doctor and study staff at the research clinic will keep records of your participation in the study. These study records will include personal information that you provide including your age, gender, medical history, the results of procedures and tests you undergo during the study or as part of the screening for the study, information about your responses while participating in the study, and other medical information related to your participation in the study. By participating in this research study, your records become part of the research records. Under federal law your study records cannot be used or disclosed by the research clinic for research purposes unless you authorize the release of those records by signing this informed consent form. You may not participate in the study unless you sign this informed consent form. If you sign this informed consent form, you will be agreeing to the disclosures of your personal information in the ways described below:

- a. Some or all of the test results and other information will be reported to R.J. Reynolds Tobacco Company, the Sponsor of this study. The Sponsor will analyze and evaluate these results and information and may report them to the U.S. Food and Drug Administration (the FDA) or other regulatory agencies in the United States and/or foreign countries. The Sponsor and the FDA will have full access to the test results and information resulting from this study, but your study records will be assigned a code number by the study team so that you will not be identified by name or other unique identifying information (such as Social Security number) in the study records that are sent to the Sponsor.
- b. In addition, personnel from the Sponsor (RJR) and its consultants (i.e., Monitors and Auditors) will be present at the research facility to monitor the conduct of the study and may review your study records and your medical records for this purpose (without your name or other unique identifying information being disclosed to them).
- c. Your study records and medical records may also be reviewed by the Independent Investigational Review Board, Inc., which is an ethics committee that reviews the conduct of human research studies.

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Protocol: CSD0904

APPROVED BY Independent IRB	
 Signature	3/1/10 Date

Initials: _____

Date: _____

The Sponsor, research clinic and the Independent Investigational Review Board, Inc. will review and use your study records only for purposes of this study. They will keep your identity confidential and, except for the disclosures described above, will not disclose your study records to other parties unless required by law. Once the research facility discloses information in your study records or medical records to the Sponsor or its consultants, the information will no longer be protected by federal law. Because of the need to release information to these parties, absolute confidentiality can not be guaranteed. However, the Sponsor and its consultants will only use your information for purposes of the study and will not disclose your study records to parties other than the FDA, unless disclosure is required by law.

If reports or articles are written about the study, you will not be identified by name in them. Your study records may be kept by the research facility for a specific period of time as required by law following the completion of the study. The data generated by the study, including data collected from you, will become the exclusive property of the Sponsor (RJR), and you will have no rights to any inventions, products, or intellectual property developed using your data. You will not have the right to review your records while the research is in progress until after the research has been completed.

As noted above, you have the right to withdraw from the study at any time for any reason. If you withdraw from the study, the information that has already been collected in your study record may continue to be used and disclosed as described above, however, no new information will be obtained or added.

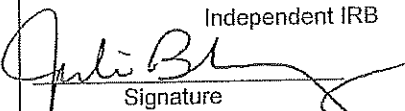
IN CASE OF INJURY

If during the course of this study, any injury occurs to you as a direct result of performed study procedures, the study Sponsor, R.J. Reynolds Tobacco Company, agrees to pay all medical expenses necessary to treat such injury (1) to the extent you are not otherwise reimbursed by medical insurance and (2) provided you have followed the directions of the Study Doctor.

Financial compensation for such things as lost wages, disability or discomfort due to injury is not covered.

You **DO NOT** waive any of your legal rights as a research participant by signing this form.

Version: 3/1/10
Protocol: CSD0904

APPROVED BY Independent IRB	
	3/1/10
Signature	Date

Initials: _____

Date: _____

CLOSING STATEMENT

You have read and understood the statements in this informed consent document. You have received satisfactory answers to all of the questions which you have asked and you willingly signed and initialed each page of this consent form. You will receive a copy of the signed informed consent. You hereby consent to be a participant in this study.

SIGNATURES

I have read in a language that I understand well, the above information. The content and meaning of this information has been explained to me. I understand the statements in this informed consent document. I hereby voluntarily consent and offer to take part in this study and authorize the use and disclosure of my medical information as described in this document.

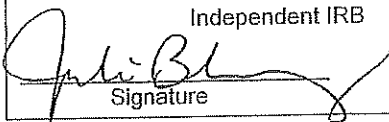
Date/Time _____
Print Research Participant Name _____
Research Participant Signature

Date/Time _____
Print Name of Person
conducting the Informed
Consent discussion _____
Signature of Person
conducting the Informed
Consent discussion

Copy of consent form given to research participant:
On (date) _____ by (initials) _____

Independent Investigational Review Board, Inc.
Approved: 11/3/09; Revised: 11/10/09, 12/8/09, 3/1/10

Version: 3/1/10
Protocol: CSD0904

APPROVED BY
Independent IRB

Signature 3/1/10
Date

Initials: _____
Date: _____