Informed Consent Form

Official Title: Effects of Cigar Flavors on Measures of Abuse Liability Among Young Adults

NCT Number: NCT0293705

Document Date: March 6, 2017

Title: Clinical laboratory evaluation of cigar flavors

VCU IRB Number: HM20007848

Investigator: Dr. Andrew Barnes

Sponsor: National Institutes of Health

This consent form may contain words that you do not understand. Please ask the study staff to explain any words that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Introduction. You are being asked to participate in a research study that is being conducted by VCU's Dr. Andrew Barnes. The purpose of the study is to understand how the availability of cigar flavors influences smoking behavior and exposure to different chemicals found in tobacco smoke.

Study Procedures. Before you join the study, we will ask you to fill out some forms about yourself, your medical history, tobacco/alcohol/drug use, and perceptions of tobacco products, and we will use a urine test(s) to make sure that you qualify to participate in the study.

If the urine tests and your answers to our questions indicate you fulfill the entry criteria, we will ask you to participate in five sessions that differ by the tobacco product used, each taking 3 hours, at the Behavioral Health Research Laboratory in Thurston House at VCU's Monroe Park campus. Each session will begin at approximately the same time each day, and will be separated by at least 48 hours.

Before each session, we will ask you to abstain from all tobacco products and all nicotine containing products (like the gum or patch) for at least 12 hours. We will ask you to take a simple breath test to make sure that you have complied with these restrictions. Our tests are not perfect, but they will be the only measures that we can accept to make certain that you have complied with the no tobacco/nicotine restrictions. We also ask that you abstain from all caffeine-containing beverages and all foods for at least one hour prior to each session.

At the beginning of each session, after you provide the breath sample used to assess compliance with the no tobacco/nicotine restrictions, you will be asked provide a saliva sample and then use a session-specific cigar or your own brand cigarette. The cigars that you use in each session will be one of four flavors (original, apple, cream, or wine). During each session we will ask you to use the cigar given to you or your own brand cigarette at two separate times and the cigar/cigarette will be attached to a computer to monitor your smoking behavior. Each time, we will ask you to take only 10 puffs, and we will tell you when to take each of these puffs. At each of these two times we need you to remain seated in a comfortable chair while you are using the products. We will also ask you to provide 3 additional saliva samples during each session (4 total per session). Throughout each session we will monitor your blood pressure using a blood pressure cuff on your arm, similar to what your doctor uses and your heart rate using sensors attached to your finger. We will also ask you to respond to several questionnaires to measure how you feel before and after you use the products. At the conclusion of the session we will ask you to complete one additional questionnaire that asks you make fifteen different choices between ten puffs of the session product and varying amounts of bonus money. One of the decisions you made will be selected at random, and you will immediately receive the results of your choice.

Benefits. You will derive no personal benefit from this. However, your participation will help us in the future as we try to understand better the effects of cigar flavorings on smoking behavior.

Alternative Therapy. This is not a therapeutic study. You have the alternative not to participate.

Risks, Inconveniences, Discomforts. You may experience some mild discomfort during the 12-hour tobacco/nicotine abstinence period before each session. Side effects from tobacco/nicotine abstinence can include irritability, anxiety, restlessness, excessive hunger, difficulty concentrating, and sleep disturbance. Though uncomfortable, these feelings are not medically dangerous. You may also experience side effects from products that contain nicotine such as acute increases in heart rate and blood pressure, sweating, lightheadedness, dizziness, nausea, and nervousness. These effects are unlikely in individuals who use cigarettes regularly. There is a risk of allergic reaction to some of the chemicals found in cigar flavors. Individuals who report food/chemical allergies that may interact with the chosen cigar flavors will be excluded from the study. You may find giving saliva samples uncomfortable but using special collection tubes should reduce this risk. If you find any side effects or procedures unacceptable, you may stop your participation at any time.

Costs of Participation. There is no cost to you for participation except for your time. Participating in this study will take about 15 hours in the laboratory.

Payment for Participation. You will be paid in cash for the time and inconvenience involved in participating in this study. You will be paid $50 for completion of the first session, $60 for session 2, $70 for session 3, $80 for session 4, $100 for session 5 for a total of $360. During the multiple choice task you may receive $0-$10.24 depending on your choices and the choice randomly selected. Additionally if lab parking is not available you will be reimbursed up to $6 per session for parking expenses only.

Total payments within one calendar year that exceed $600 will require the University to annually report these payments to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

Pregnancy. Every effort will be made to have women enter this study on an equal basis with men. Tobacco use may be harmful to a fetus, and pregnant women may not participate in this study. If you suspect that you are pregnant, or if you are currently breast-feeding a baby, please inform the investigator now and do not participate. We will conduct a urine pregnancy test during the screening evaluation to ensure that pregnant women do not participate.

Confidentiality of Records. We will not tell anyone the answers that you give us; however, information from the study and the consent form signed by you may be looked at or copied for research or legal purposes by the sponsor of the research, or by Virginia Commonwealth University.

Confidentiality of your records will be maintained by keeping all data in a locked file and in a coded and password-protected database. Release of this information will be withheld, consistent with the law, unless you give permission to release information. The information obtained in this study may be published, but your identity will not be revealed.

Withdrawal. Participation is voluntary. The investigators will answer any questions that you may have. You are free to withdraw your consent and discontinue participation at any time. If you choose

not to participate or to discontinue your participation, this choice will in no way affect any medical care you receive now or in the future at this institution. In addition, your participation or discontinuation will in no way affect your status if you are a student or employee of VCU. If during the course of the study you experience adverse effects or if you do not comply with the study restrictions, your participation may be stopped by Dr. Barnes without your consent. Any significant new findings which develop during the course of the research study that may affect your willingness to continue to participate will be provided to you.

If an Injury Happens. Virginia Commonwealth University and the VCU Health System (formerly known as the Medical College of Virginia Hospitals) have no plan for providing long-term care or compensation in the event that you suffer injury as a result of your participation in this research study. If you are injured or if you become ill as a result of your participation in this study, contact a research assistant immediately. We will arrange for short-term emergency care or referral if it is needed. Fees for such treatment may be billed to you or to appropriate third party insurance. Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this study.

Current Telephone Numbers. You can call Dr. Barnes at 804-827-4361 for information about the research or about research-related injury.

Participants' Rights Information. If you have questions about your rights as a research participant, you may contact:

Office of Research
Virginia Commonwealth University
Virginia Biotechnology Research Park, BioTech One
800 East Leigh Street, Suite 3000, P.O. Box 980568
Richmond, VA 23298-0568
Telephone: 804-827-2157

If you agree to join this study, please print and sign your name below. You will receive a copy of this consent form.

Consent. I have read this consent form. I understand the information about this study. All my questions about the study and my participation in it have been answered. I freely consent to participate in this research study.

By signing this consent form I have not waived any of the legal rights which I otherwise would have as a participant in a research study.

_____
Participant's Printed Name

_____ _____
Signature of Participant Date

_____ _____
Signature of Person Performing Consent Date

_____ _____
Signature of Investigator Date