RUTGERS
School of Arts and Sciences

Department of Psychology
School of Arts and Sciences
Rutgers, The State University of New Jersey
1 Spring St., Suite 200
New Brunswick, NJ 08901

samantha.farris@rutgers.edu
teresa.leyro@rutgers.edu

CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: A Study of Attention, Physiology, and Smoking-Precipitated Reinforcement

Principal Investigators: Samantha Farris, Ph.D. and Teresa Leyro, Ph.D.

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not. You are invited to participate in this study because you have identified as a daily cigarette smoker between the ages of 18-55 years old.

The **purpose of this study** is to evaluate different aspects of physiology and attention during cigarette smoking. If you take part in the research, you will be asked to commit to 2 consecutive lab visits, with each visit spanning a maximum of two hours. You will be randomized to complete one of two different computerized tasks. During the computer task, you will be given the opportunity to smoke while we also monitor your physiological activity.

Possible harms or burdens of taking part in this study are limited to mild skin discomfort from use of stick-on electrodes to measure physiology.

An alternative to taking part in the research study is to not participate. You may withdraw at any point during the study without penalty or prejudice.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to participate. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to receive answers you completely understand. After your questions have been answered, and you continue to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Samantha Farris, Ph.D. and Teresa Leyro, Ph.D. are Professors at Rutgers University in the Psychology Department, and the Principal Investigators of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. Dr. Samantha Farris may be reached at 848-445-8843 or samantha.farris@rutgers.edu. Dr. Leyro can be reached at 848-445-8842or teresa.leyro@rutgers.edu.

Sponsor of the Study: National Institute on Drug Abuse

Why is this study being done?
This study is designed to evaluate the different aspects of physiology and attention training during smoking.

Who may take part in this study and who may not?
You may participate in this study if you are between the ages of 18 and 55, and smoke more than 8 cigarettes per day. The first cigarette of the day must be within the first 30 minutes of waking and the cigarette you smoke during in-lab visits must be the second cigarette of the day. You will not be eligible to participate in this study if you are: 1. currently receiving smoking cessation counseling or taking medication to help you quit, 2. have severe visual, hearing or cognitive impairments, or 3. if you have a medical condition or are taking a medication that may affect your physiology.

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Why have I been asked to take part in this study?
You have been identified as a daily smoker.

How long will the study take and how many subjects will take part?
We expect 80 daily smokers to complete our study. The study includes a virtual baseline appointment (what we are doing today). Then, if you are eligible, you will be asked to complete two in-lab visits. These visits will take place over two consecutive days, and each visit will last approximately 2 hours.

What will I be asked to do if I take part in this study?

During your virtual baseline visit, you will be asked to:

- Meet with a trained research staff member to go over several assessments with you. These will include a few brief surveys of your medical history and smoking habits, and a diagnostic interview to assess whether or not you are eligible for study participation, and additional surveys.
- If you are eligible, you will be invited to participate in the in-lab portion of the study that involves two visits.

During your first in-lab visit, you will be asked to:

- Complete a carbon monoxide analysis. You will be asked to blow air into a tube that is attached to a machine. This determines the amount of carbon monoxide, a byproduct of cigarettes, that remains in your lungs after smoking. You will be asked to complete a carbon monoxide analysis once during the lab visit.
- Complete a height and weight measurement, and blood pressure assessment.
- Complete a 30-minute computer task, where you will be hooked up to stick-on sensors attached to a computer that will measure your heart rate and breathing. During the computer task, you will be asked to smoke one cigarette using a hand-held device that measures how you smoke.
- Complete brief surveys about your mood and smoking craving at various times throughout the visit.

During your second visit, you will be asked to complete the same activities as completed in the first in-lab visit.

What are the risks of harm or discomforts I might experience if I take part in this study?
Overall, the risks in this study are very minimal and may include the following:

- There is a slight risk of feeling emotional distress and frustration when engaging in diagnostic interviews due to the sensitive nature of questions. You may also experience induced distress or frustration as a function of difficulty or attentional demand when completing the computer task. Study personnel are experienced and sensitive to this issue and will cease testing if you are experiencing excessive frustration.
- You may also experience physical discomfort. Attachment of electrodes, although passive, may result in some discomfort upon removal. However, removal is no more painful than removing an adhesive bandage.
- Finally, there is a very slight risk that your confidentiality could be violated. To reduce the risk of violating confidentiality, several steps will be taken. Only IRB approved members of the research team will have access to the data. Data will only be accessed when coded, entered, or audited. All data will be stored in locked cabinets within locked rooms. Based on these procedures, we anticipate that the risk to confidentiality being violated is very low.

Are there any benefits to me if I choose to take part in this study?
Although no direct benefits are expected, potential benefits include helping researchers better understand factors that influence smoking behavior.

What are my alternatives if I do not want to take part in this study?
An alternative is to not participate in this research study. You may withdraw at any point during the study without

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penalty or prejudice.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study.

Will there be any cost to me to take part in this study?
Aside from the time associated with coming to the New Brunswick Campus of Rutgers University, there are no expected costs of participation.

Will I be paid to take part in this study?
In return for your time and effort required to take part in this study, you will receive $30 for the baseline portion of the study (today's visit). If you are eligible, you will receive $70 for completing the first in-lab visit, an additional $100 for completing the second in-lab visit, and a $50 study completion bonus. In total, you will earning a up to $250 for your participation. Completing the in-lab visits is dependent on eligibility.

How will information about me be kept private or confidential?
Information collected during your participation in this research is confidential. Private health information including data regarding physical health, mental health, and substance use will be linked to an arbitrary study identification number. However, a limited amount of information will be stored in a password-protected file in such a manner that will link your identity and your responses. The information in this file is limited to your assigned study ID, first and last name, your contact information (phone number and email address), and date of participation. Please note that this information will be stored separately from study data coded by your arbitrary study number.

However, if you express suicidal thoughts or plans of any type, or if you express intent to seriously harm others, in the answers to our questions, we will do all that we can to maintain your safety and the safety of others, in which case the confidentiality limits described may be broken. To the best of our ability, we will seek your cooperation in making the report and provide you with referral information to local providers in the community with expertise in the treatment of problems related to your expression of intent to harm yourself or others.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The research team and the Institutional Review Board at Rutgers University, who is responsible for supervising our research, are the only parties that will be allowed to see the data. If a report of this study is published, or the results are presented at a professional conference, data will be presented anonymously. Per Federal Regulations, study data will be retained for six years at which point the file linking participant names to arbitrary study IDs will be destroyed and remaining data will be anonymized.

This research is covered by a Certificate of Confidentiality. Researchers with this Certificate may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to

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an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of harm to self or others as well as reports of child and elderly abuse and neglect.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Samantha Farris, Ph.D. at Rutgers School of Arts and Sciences, 1 Spring St., Suite 200 or via email at samantha.farris@rutgers.edu.

Who can I contact if I have questions?
If you have questions about taking part in this study or if you feel you may have suffered a research related injury, you can contact the Principal Investigators: Samantha Farris, Ph.D., Psychology Department, at 848-445-8843 or samantha.farris@rutgers.edu or Teresa Leyro, Ph.D., Psychology Department, at 848-445-8842 or Teresa.leyro@rutgers.edu.

If you have questions about your rights as a research subject, you can contact the Rutgers IRB Director at: Arts and Sciences IRB, 335 George St., Liberty Plaza Ste. 3200, New Brunswick, NJ 08901 (732) 235-2866 or the Rutgers Human Subjects Protection Program at (973) 972-1149, email us at humansubjects@ored.rutgers.edu., or write us at 65 Bergen St., Suite 507, Newark, NJ 07107.

AGREEMENT TO PARTICIPATE

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____Date: _____

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CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: A Study of Attention, Physiology, and Smoking-Precipitated Reinforcement

Principal Investigators: Samantha Farris, Ph.D. and Teresa Leyro, Ph.D.

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not. You are invited to participate in this study because you have identified as a daily cigarette smoker between the ages of 18-55 years old.

The **purpose of this study** is to evaluate different aspects of physiology and attention during challenging situations and during cigarette smoking. If you take part in this part of the research, you will be asked to prepare a short speech for a set amount of time. The researchers will give you a topic and then allow you to prepare your speech alone. After the allotted time, you will be asked to give your speech in front of two trained evaluators. Your speech will be videotaped for purposes of studying the content of your speech and your non-verbal behavior during the speech.

Possible harms or burdens of taking part in this portion of the study are limited to emotional discomfort.

An alternative to taking part in the research study is to not participate. You may withdraw at any point during the study without penalty or prejudice.

The information in this consent form will provide more details about this portion of the research study and what will be asked of you if you choose to participate. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to receive answers you completely understand. After your questions have been answered, and you continue to take part in this portion of the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

This consent form is in addition to the previous forms that you signed at the beginning of this study and in no way replaces it, but instead, adds to it. All information about risks, benefits, information disclosure, confidentiality, and general participant rights pertain to this form as well. If you would like, you may also review your copy of the consent form that you signed previously today, or you may request another copy from the researcher. If you have any questions, you should ask a member of the research team now.

Who is conducting this study?
Samantha Farris, Ph.D. and Teresa Leyro, Ph.D. are Professors at Rutgers University in the Psychology Department, and the Principal Investigators of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. Dr. Samantha Farris may be reached at 848-445-8843 or samantha.farris@rutgers.edu. Dr. Leyro can be reached at 848-445-8842or teresa.leyro@rutgers.edu.

Sponsor of the Study: National Institute on Drug Abuse

Why is this study being done?
This study is designed to evaluate the different aspects of physiology and attention during smoking and challenging situations.

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You may participate in this study if you are between the ages of 18 and 55, and smoke more than 8 cigarettes per day. The first cigarette of the day must be within the first 30 minutes of waking and the cigarette you smoke during in-lab visits must be the second cigarette of the day. You will not be eligible to participate in this study if you are: 1. currently receiving smoking cessation counseling or taking medication to help you quit, 2. have severe visual, hearing or cognitive impairments, or 3. if you have a medical condition or are taking a medication that may affect your physiology.

Why have I been asked to take part in this study?
You have been identified as a daily smoker.

How long will the study take and how many subjects will take part?
We expect 80 daily smokers to complete our study. This portion of the study will take place during your 2-hour visit today.

What will I be asked to do if I take part in this study?

During your second visit, you will be asked to:

- Engage in a mild stress task (i.e., giving a speech). You will be asked to prepare a short speech for a set amount of time. The researchers will give you a topic and then allow you to prepare your speech alone. After the allotted time, you will be asked to give your speech in front of two trained evaluators. Your speech will be videotaped for purposes of studying the content of your speech and your non-verbal behavior during the speech.

What are the risks of harm or discomforts I might experience if I take part in this study?
Overall, the risks in this study are very minimal and may include the following:

- The risk associated with this part of the study is emotional discomfort. Study personnel are experienced and sensitive to this issue and will cease testing if you are experiencing excessive frustration. Should you experience excessive discomfort at any point during this experiment, you may choose to end your participation in the study, and you will be fully compensated for your time spent during the study.

Are there any benefits to me if I choose to take part in this study?
Although no direct benefits are expected, potential benefits include helping researchers better understand factors that influence smoking behavior.

What are my alternatives if I do not want to take part in this study?
An alternative is to not participate in this research study. You may withdraw at any point during the study without penalty or prejudice.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study.

Will there be any cost to me to take part in this study?
Aside from the time associated with coming to the New Brunswick Campus of Rutgers University, there are no expected costs of participation.

Will I be paid to take part in this study?

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In return for your time and effort required to take part in this study, you will receive $100 for completing the second in-lab visit (today's visit), which includes the speech task.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Samantha Farris, Ph.D. at Rutgers School of Arts and Sciences, 1 Spring St., Suite 200 or via email at samantha.farris@rutgers.edu.

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AGREEMENT TO PARTICIPATE

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this portion of the study.

Subject Name (Print):_____

Subject Signature:_____Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____Date: _____