Informed Consent to Participate in a Research Study

TITLE OF STUDY: Afferent neurocardiac signals, cue reactivity, and cognitive control
Principal Investigators: Brandon Alderman Ph.D. & Marsha Bates, 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.

The **purpose of the research** is to better understand how the cardiovascular system and brain work together when completing cognitive tasks that involve picture cues related to alcohol, emotion, and everyday objects. If you take part in the research, you will be asked to complete some demographic, psychological, and drinking behavior questionnaires. Before you complete three cognitive tasks, you either will complete a paced breathing task or a color viewing task while we record your heart and brain activity. This will consist of placing sensors on your skin and an electrode cap on your head. These procedures are not invasive and have no known risks. You will be asked to attend two sessions in the laboratory, about one week apart, and each will last approximately 2-2.5 hours.

Possible harms or burdens of taking part in the study may be that you will be asked to answer some sensitive questions such as your substance use and any illness. Although very unlikely, the paced breathing may cause you to temporarily feel dizzy or lightheaded, but this goes away as soon as you stop paced breathing.

An alternative to taking part in the research study: Your alternative to taking part in the research study is not to take part in it.

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 take part in it. 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 be given answers you completely understand. After all of your questions have been answered and you wish 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?

Dr. Brandon Alderman and Dr. Marsha Bates are the Principal Investigators of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team. Dr. Brandon Alderman may be reached at (848) 445-9336 or alderman@rutgers.edu. Dr. Marsha Bates may be reached at (848) 445-3559 or mebates@rutgers.edu. This study is supported by a research grant from the National Institutes of Health.

The Principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?
The purpose of this study is to better understand how the cardiovascular system and the brain work together during performance of several cognitive tasks that involve pictures related to alcohol, other beverages, emotions, people, and objects.

Who may take part in this study and who may not?
Eligible participants may be male or female adults between the ages of 18 and 35 years old at the time of data collection. Those who have (1) a history or presence of diagnosed psychiatric disorders, neurological disorders, or head injury resulting in a loss of consciousness, (2) any serious medical condition, and/or (3) uncorrected visual impairment or color blindness will be excluded from the study.

Why have I been asked to take part in this study?
You have been asked to participate in this study due to your eligibility through the screening survey that you have previously completed.

How long will the study take and how many subjects will take part?
Approximately 100 individuals will be recruited for participation in this study. The study will take part over two sessions conducted approximately one week apart and each session will last approximately 2-2.5 hours in the laboratory.

What will I be asked to do if I take part in this study?
You will be asked to fill in some demographic, psychological, and drinking behavior questionnaires and to complete 3 cognitive tasks while we measure your physiological activity using sensors placed on your skin and an electrode cap placed on your head. Before each task, you will perform a paced breathing task or a visual color block task for 5 minutes. Once connected you will remain in the testing room until the end of the experiment. Before each of the two sessions begin, you will be asked to provide a breath sample by blowing into a tube, to verify that you do not have any alcohol in your system. During each session, you will be asked to complete several tasks which will be presented on the computer screen and you will be asked to follow the instructions and press the corresponding keys to provide your responses during the tasks. During one of the sessions, you will be asked to perform a paced

breathing technique which you will be taught during the study session; during the other session, you will perform a color block task.

What are the risks of harm or discomforts I might experience if I take part in this study?
There are no known risks of harm or discomfort experienced if you take part in this study. However, you may become uncomfortable while answering sensitive substance-related questions and although unlikely, the paced breathing may cause you to temporarily feel dizzy or lightheaded. This is rare and goes away as soon as you stop the slow breathing procedure. Some of the pictures that you will be asked to view may be embarrassing or uncomfortable to look at (e.g., accidents, criminal behavior, injury, sexuality). These pictures are from a standardized set and have been used in many other experiments. Nonetheless, if at any time you wish to stop viewing the pictures, let us know and we will end the task. You may also feel a slight discomfort during the removal of the ECG electrodes at the end of the study session and you will be asked about any potential skin irritation to topical lotions, gels, etc. before we place the electrode cap.

Are There Any Benefits To Me If I Choose To Take Part In This Study?
It is possible that you will not receive any direct benefits from participating in this study. The indirect benefits of taking part in this study may be contributing to knowledge about how the heart and brain work together to process information and whether rate of breathing influences this process.

What Are My Alternatives If I Do Not Want To Take Part In This Study?
Your alternative is not to take part in this study.

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. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will There Be Any Cost To Me To Take Part In This Study?
There will be no cost to participate.

Will I Be Paid To Take Part In This Study?
You will receive $50.00 per session in the form of an Amazon gift card for your participation in this study. You will receive this compensation after you complete each session. If you withdraw from the study at any time before the end of the session, you will receive compensation proportional to your time spent in the laboratory.

How Will Information About Me Be Kept Private Or Confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Breach of confidentiality is a risk of harm but a data security plan is in place to minimize such a risk. Your identifiable information will not be stored with your responses. Instead, your responses will be assigned a subject # which will be stored separately from your name so others will not know which responses are yours. We will securely store the key code linking your responses to your identifiable information in a separate password protected file.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require, such as laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

What Will Happen To Information Collected For This Research After The Study Is Over?

After information that could identify you has been removed, de-identified information collected for this research may be used by or distributed to investigators for other research without obtaining additional informed consent from you. After a period of 6 years, a separate password protected file containing your identifiable information will be destroyed.

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 and with Rutgers University 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 Dr. Brandon Alderman at alderman@rutgers.edu.

Who Can I Contact If I Have Questions?

If you have questions about taking part in this study, you can contact either of the Principal Investigators: Brandon Alderman at (848) 445-9336 or alderman@rutgers.edu; Dr. Marsha Bates at (848) 445-3559 or mebates@rutgers.edu.

If you have questions, concerns, problems, information or input about the research or would like to know 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) 972-3608 or (732) 235-9806, or email them at human-subjects@research.rutgers.edu.

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 Name (Print):_____

Signature:_____ Date: _____

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School of Arts and Sciences

Division of Life Sciences
Department of Kinesiology and Health

ADDENDUM: CONSENT TO SHARE YOUR DE-IDENTIFIED DATA

TITLE OF STUDY: Afferent neurocardiac signals, cue reactivity, and cognitive control
Principal Investigators: Brandon Alderman, PhD and Marsha Bates, PhD

STUDY SUMMARY: You agreed to take part in the Afferent Neurocardiac Signaling (ANS) Study. We are asking an additional consent to share your data, after de-identifying it, with the National Institute on Alcohol Abuse and Alcoholism (NIAAA) Data Archive. NIAAA is part of the National Institutes of Health (NIH), which funds health-focused research, including this Study.

De-identifying data means that all personal information that could identify you is removed and replaced with a code number. To generate the code number, we will ask you to provide specific information from your most recent birth certificate (full name, date of birth, location of birth, and sex). A code number is made using a cryptographic hashing algorithm and a Global Unique Identifier (GUID) is assigned to you. The data provided by you as part of your participation in the ANS Study is then linked to this GUID and submitted to the NIAAA Data Archive. More information is available online at https://nda.nih.gov/niaaa.

There are risks to sharing data, but the researchers at Rutgers and the personnel at NIH have protocols in place to reduce such risks. There are no direct benefits from sharing data, but you are supporting the goal of the NIAAA Data Archive to accelerate research on alcohol use and health. If you decide any time after today that you do not want your data to be included in the NIAAA Data Archive, you can contact us and we will tell NIAAA Data Archive to stop sharing your study data from that point forward.

Please note that you can still participate in the Afferent Neurocardiac Signaling (ANS) study even if you decide that you do not want your data to be added to the NIAAA Data Archive.

CONTACT: Principal Investigator – Brandon Alderman, Smithers Hall Room 217C, 607 Allison Road, Piscataway, NJ 08854 TEL: 848-445-9336. EMAIL: alderman@kines.rutgers.edu
Rutgers Human Subjects Protection Program - TEL: 732-235-2866
EMAIL:IRBOffice@research.rutgers.edu

Do you agree to allow the principal investigators of the ANS study to share your de-identified data with the National Institutes of Health NIAAA Data Archive as part of a project to centralize research data and make it available to other researchers for the purpose of accelerating learning?

☐ Yes, I DO agree to share my de-identified data with the NIAAA Data Archive

☐ No, I DO NOT agree to share my de-identified data with the NIAAA Data Archive

Subject Name:_____

Subject Signature:_____ Date:_____

If you selected "Yes", please see the following page and provide the information listed.

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OF NEW JERSEY

AGREEMENT TO SHARE DE-IDENTIFIED DATA

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 share data from this study.

Please record your information exactly as it appears on your most recent birth certificate.

First Name: _____

Middle Name: _____

Last Name: _____

Date of Birth: _____ / _____ / _____

Sex Assigned at Birth: _____

City/Municipality of Birth: _____

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 Obtaining Consent Name (Print):_____

Signature:_____ Date:_____