RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Genetic and Neural Factors in Alcohol-Related Cognition

VCU IRB NO.: HM20013938

INVESTIGATOR: Dr. David Chester

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the study staff to explain any information in this consent document that is not clear to you.**

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

PURPOSE OF THE STUDY

This study is about how family risk and brain factors impact your cognitive processes and behavior after recent alcohol consumption. Your participation in this project will contribute to a better understanding of family and biological factors that influence alcohol misuse. This study will be completed in a single three-hour laboratory visit. YOU WILL NOT CONSUME ALCOHOL AS PART OF THIS STUDY.

You are being invited to take part in this research study because you are 21 years old or older and you meet comfort and safety criteria for an MRI environment.

DESCRIPTION OF THE STUDY AND YOUR INVOLVEMENT

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered and understand what will happen to you.

Today, you will be asked to:

1. Complete a questionnaire intended to screen you for safety and comfort with both our MRI procedures. This will include a pregnancy test for participants who were assigned a female sex at birth.
2. Practice the computer tasks that you will complete in the MRI scanner.

3. Enter the MRI scanner and complete a series of computer tasks (approximately 10 minutes per task) that include noise blasts while undergoing brain scans that measure the structure and functioning of your brain*. The entire MRI scan will last approximately 50-60 minutes.
4. Exit the MRI scanner and complete a battery of questionnaires in a nearby room. The battery of questionnaires consists of roughly seven hundred questions and include questions about your personality and behavior, such as: narcissism, sadism, spitefulness, vengeance, psychopathy, empathy, aggression, illegal drug use, illegal activities, and history of crime (you can skip any question that you do not want to answer). We expect that you will spend 60-90 minutes completing these questionnaires.

*MRI scans are a very common and safe form of brain imaging that use magnetic waves to record images of your body. While you lay inside of a large MRI machine, which looks like a large tube, we will pass magnetic waves through your head which can measure the structure and function of your brain. These procedures are very safe (for more information see the Risks and Discomforts section below).

Significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you. Approximately 202 people will participate in this study.

RISKS AND DISCOMFORTS

To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life. You may find some questions we ask you (or some procedures we ask you to do) to be upsetting or stressful. You do not have to answer any questions that you do not want to, and you may leave the study at any time. If you become upset, the study staff will give you names of counselors to contact so you can get help in dealing with these issues.

A computer task that you will complete in the MRI scanner entails listening to loud noises that are uncomfortable but are not unsafe. The human threshold for hearing damage in 140 decibels and the loudest that these noises can get is 105 decibels, well below this hearing damage threshold.

The risks and discomforts of participating in the MRI study are outlined in the table below. Most of the risks are not serious, though there is a chance that we could find a serious abnormality in the structure of your brain. If an abnormality is found, and is indicative of a serious condition, the Principal Investigator (D. Chester) will contact you. A medical professional will be available to consult with you on how to proceed with this issue. It is important to note that the brain scans conducted in this study are NOT of clinical/diagnostic quality. As such, a scan from our study cannot be used to make a conclusive, medical diagnosis and a scan from this study that does not reveal any abnormalities should NOT prevent

you from seeking medical testing if you are exhibiting symptoms of a suspected neurological issue.

If an irregularity in your brain is found, the evaluation for this abnormality could lead to significant anxiety, costs and risks not included in this research study. Some abnormalities could affect your insurability or employability.

In addition to the risks below, you may experience a previously unknown risk or side effect:

Possible Risk/Side Effect	How often has it occurred?	How serious is it?	Can it be corrected?
Claustrophobia	It occasionally occurs	Can be treated	Yes, participant is removed from the magnet
Dizziness	It occasionally occurs	Not serious	Yes, change body positions slowly within the magnetic field
Loud noise	It is expected to occur	Not serious	Yes, participants wear ear protection
Detection of a brain abnormality	It rarely occurs	May be serious	Participant is told to contact their primary care physician

BENEFITS TO YOU AND OTHERS
You may not get any direct benefit from this study, but, the information we learn from people in this study may help us better understand human biology and behavior.

In general, we will not provide you with any individual research results.

COSTS
There are no costs for participating in this study other than the time you will spend completing the study.

PAYMENT FOR PARTICIPATION
You will receive $60 in cash at the end of this study session. If you choose to withdraw from the study early, you will receive $25 per hour that you participated in this study at the time you choose to withdraw from the study, rounding hours upwards.

ALTERNATIVES
If you do not wish to complete this study, you can sign-up for other studies.

CONFIDENTIALITY

Potentially identifiable information about you will consist of your responses to a series of questionnaires, your responses to the computer tasks you perform in the MRI scanner, and images of your head and brain. Data is being collected only for research purposes.

In the future, identifiers might be removed from the information and samples you provide in this study, and after that removal, the information/samples could be used for other research studies by this study team or another researcher without asking you for additional consent.

All the other data listed above will be identified by ID numbers, not names, and stored on password-protected computers in a locked research area. All personal identifying information will be kept in password protected files and these files will be deleted immediately once the study is completed. Other records such as consent forms and data consent forms will be kept in a locked file cabinet for 5 years after the study ends and will be destroyed at that time. Your de-identified data files will be kept indefinitely by our laboratory. For the sake of transparency, your de-identified responses to today's computer questionnaire and tasks will be made publicly-available through an online database called the Open Science Framework (stripped of all demographic information such as age, race, ethnicity, gender, and sex). Further, your brain scans will be combined with other participants' brain scans and these aggregated brain images will be made publicly-available through an online database called NeuroVault. Your individual MRI scans will never be made available to anyone outside of approved study personnel.

What we find from this study may be presented at meetings or published in papers, but your name or any other identifying information will never be used in these presentations or papers.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person

obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide to not participate in this study. Your decision not to take part will involve no penalty or loss of benefits to which you are otherwise entitled. If you do participate, you may freely withdraw from the study at any time. Your decision to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled. If you would like to withdraw your data you can do so by contacting the Principal Investigator.

Your participation in this study may be stopped at any time by the study staff without your consent. The reasons might include:

- the study staff thinks it necessary for your health or safety;
- you have not followed study instructions
- administrative reasons require your withdrawal.

QUESTIONS

If you have any questions, complaints, or concerns about your participation in this research, contact:

Dr. David Chester
dschester@vcu.edu
804-828-7624

The researcher named above is the best person to call for questions about your participation in this study.

If you have any general questions about your rights as a participant in this or any other research, you may contact:

Office of Research
Virginia Commonwealth University
800 East Leigh Street, Suite 3000
Box 980568
Richmond, VA 23298
Telephone: (804) 827-2157

Contact this number to ask general questions, to obtain information or offer input, and to express concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk with someone

else. General information about participation in research studies can also be found at http://www.research.vcu.edu/human_research/volunteers.htm.

CONSENT

I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing to participate in this study. I will receive a copy of the consent form once I have agreed to participate.

Participant name printed	Participant signature	Date

Name of Person Conducting Informed Consent Discussion (Printed)

Signature of Person Conducting Informed Consent Discussion	Date

Principal Investigator Signature (if different from above)	Date