

## **INFORMED CONSENT DOCUMENT**

**Project Title:** Characterizing Alcohol Risks in Development (CARD)

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This consent form describes the research study in which you are being asked to participate. The purpose of the form is to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the researchers for more information or clarification.
- You should discuss your participation with anyone you choose, such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

### **WHAT IS THE PURPOSE OF THIS STUDY?**

This is a research study. The purpose of this research study is to increase scientific understanding of the factors that can increase or decrease the likelihood that adolescents and young adults will drink alcohol and experience negative consequences from drinking.

We are inviting you to participate in this research study because, based on your responses to the online eligibility screener, you met the eligibility criteria for being in the study (for example, you or someone you know has consumed alcohol in the past year; you have no history of neurologic disease or injury; you are age 14-19).

### **HOW MANY PEOPLE WILL PARTICIPATE?**

Approximately 480 people will take part in this study at the University of Iowa. All will be between the ages of 14-19 years old when they start the study.

### **HOW LONG WILL I BE IN THIS STUDY?**

If you agree to take part in this study, your involvement will last for up to 30 months (2.5 years). You will be asked to visit the research lab three times and to complete some online questionnaires in-between lab visits. Each lab visit will last approximately 3-3.5 hours. Lab visits will be separated by 15 months. Approximately 5 months and 10 months after the first and second lab visits, you will be asked to complete some questionnaires online.

### **WHAT WILL HAPPEN DURING THIS STUDY?**

You will be asked to visit the research lab three times and to complete some online questionnaires in-between lab visits. Each lab visit is expected to last 3-3.5 hours. During each lab visit, you will be asked

to complete several computer-based tasks and games. These will include:

- A beverage-smelling task in which we will ask you to rate how much you would like to consume different beverages, including alcohol. (Researchers will monitor you by video to make sure you don't consume any of the beverages.)
- Picture-viewing tasks including pictures of beverages, everyday objects, and shapes. In one of these tasks, you will be asked to judge whether pictures of beverages are alcoholic or nonalcoholic by pressing one of two buttons. In another task, you will see a series of pictures of various kinds of liquids and asked to pull or push on a video game joystick controller to indicate the direction (left or right) that each image is rotated.
- Reward-learning tasks in which you will be asked to make a choice (for example, between two faces or two doors) to try to win small rewards.
- Several tasks to test your cognitive abilities (visual detection, memory, reaction time).
- A task where you will be asked to look at sets of faces displaying different facial expressions.

During some of these tasks, a set of harmless sensors will be placed on your scalp and face. These sensors will record the tiny electrical activity in your brain, known as the EEG, as you view and respond to stimuli (e.g., pictures) presented on the computer monitor. The sensors **will not** harm you in any way. Sensor gel will be inserted into each sensor prior to recording to ensure a good connection. This gel easily washes out with water. The lab has a deep sink with a shower wand attachment in a private room where you can wash the gel from your hair afterwards.

The EEGs will not be read clinically, which means they will not be read by a person with clinical expertise in EEG interpretation for the purpose of detecting neurological abnormalities. If you develop neurological symptoms or concerns, you should seek care from a healthcare provider as you normally would.

Prior to each lab visit, we will send you a link to a secure questionnaire to complete before you come to the lab. The questionnaire will ask about your (and your friends') drinking and reasons for drinking, your personality and typical responses in different situations, your relationships with friends and family, and related issues. Some of the questions might make you feel uncomfortable. For example, "Have you ever cheated on a test at school?", "How often do you and your mom quarrel with each other?" or "Did you ever pass out after drinking alcohol?" You can skip any questions you prefer not to answer.

Then, approximately 5 months and 10 months after the first two lab visits, we will again send you a link to a secure questionnaire.

Do not come to the research site intoxicated. You will blow into a breathalyzer at the start of each session to ensure your breath alcohol concentration (BrAC) is 0.000. If your BrAC registers over 0.000, you will be asked to reschedule your session, and an Uber or Lyft will be provided to transport you home.

This is not a treatment study. You will not be provided with the results of this study. Your research data will not be accessible to you because your data has no validity or reliability outside of the lab. Your research data can only be accessed via a Court Order.

### **WHAT ARE THE POSSIBLE RISKS OF PARTICIPATING IN THIS STUDY?**

Participation in this study is associated with greater than minimal risks. Some possible risks include:

1. Getting tired or uncomfortable from completing the questionnaires and tasks and possibly from thinking about past stressors. There is a chance that you may feel uncomfortable answering questions

about some aspects of your personal life.

- You will be encouraged to take short breaks between the tasks. If you prefer not to answer certain questions, you can skip them. Referrals are available for mental health resources at the University of Iowa and in the surrounding community.
2. During the EEG recording, there is a small possibility of mild skin irritation (redness) where the sensors contact the skin. However, this is rare and temporary. If you are afraid of needles, there is a chance that you may feel uncomfortable at the sight of the plastic syringes that we use to put gel in the EEG cap. These syringes are not sharp; they contain no needle whatsoever. They are essentially a plastic container used to place gel on the sensors.
- We make every effort to make the lab session as comfortable as possible. We will provide you with rest breaks in-between each of the tasks, during which you will be offered refreshments (water or juice and cookies). Should you experience more than mild discomfort and wish to take a break or discontinue participation, you may do so at any time without penalty.
3. Breach of confidentiality. Although remote, there is the possibility of breach of confidentiality of information we collect from you.
- The researchers have experience dealing with sensitive information and assuring that data are adequately protected. We take several steps to ensure your confidentiality. All information you provide will be associated with an arbitrary participant ID number rather than your name. Links between potentially sensitive information concerning health information or alcohol and drug use and personal identifiers such as your name and any code number used for the study will be destroyed at the conclusion of this study (within five years from now); that is, information will become untraceable. As per University of Iowa policy, we will retain research records for at least seven years following completion of the study (records will not include personally identifying information, such as names or addresses).
4. Legality of substance use. Consumption of alcohol is illegal for persons under the age of 21, and use of some drugs is illegal for all persons. Thus, reporting on alcohol and drug use could expose you to legal risks.
- **This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH).** This Certificate ensures the ability of all persons working on this study to protect the privacy of participants and their data. The researchers cannot disclose identifying information about you or your participation in this research to any person or entity not connected with the research without your specific consent. Information protected by this Certificate cannot be disclosed to anyone except (a) if there is a federal, state, or local law that requires disclosure (such as to report child abuse); (b) if you have consented to the disclosure; or (c) if it is used for other scientific research, as allowed by federal regulations protecting research subjects. More about the Certificate and the protections it provides is given in a later section of this document.
5. Unforeseen risks. Because this is a new research study, there may be additional risks that we cannot identify at this time. We will tell you about any new information we learn about potential risks that could affect your decision to continue to participate in this study.

### **WHAT ARE THE BENEFITS OF THIS STUDY?**

We do not know if you will benefit personally from being in this study. We hope that, in the future, other people will benefit from this study because of the discoveries we make about factors that increase or decrease the risk of developing problems with alcohol.

### **WILL IT COST ME ANYTHING TO BE IN THIS STUDY?**

It will not cost you anything to be in this study. However, you might experience costs associated with your transportation to the lab or taking time off work to come to the lab.

### **WILL I BE PAID FOR PARTICIPATING?**

You will be compensated for being in this research study. Compensation will be in the form of e-gift cards that you can use to purchase merchandise and services available on Amazon.com. To compensate you for your time and effort, you will receive up to \$495 in e-gift cards. Specifics of study compensation are as follows:

- \$10 for completing the online eligibility screener, and an additional \$25 for completing the online questionnaire packet prior to each lab visit (total = \$85).
- \$90 for participation in each of the three lab visits, which are expected to last four hours each. To thank you for coming back, bonuses of \$30 per session will be paid for participating in the 2nd and 3rd lab visits (total = \$330).
- \$20 for each of the online questionnaire packets, to be completed 5 and 10 months after the first two lab sessions (total = \$80).
- You will also receive small prizes in the lab for completing the tasks and small gifts simply for being a study participant. These prizes and gifts may include drawstring bags, stress balls, hats, playing cards, t-shirts, and water bottles.

#### **About the compensation:**

- You will be paid after each study component is completed within 7 business days (except for the eligibility screener, which will be paid at the same time as the first lab visit).
- If you decide to withdraw from participation before completing the study, your payment will be pro-rated based on the amount of the study you have completed. For example, if you decide to withdraw halfway through the first lab session, you will be paid \$45 for that session plus \$10 for completing the online eligibility screener and \$25 for completing the online questionnaire packet, for a total payment of \$80.

### **WHO IS FUNDING THIS STUDY?**

This study is being funded by the National Institute on Alcohol Abuse and Alcoholism (NIAAA), a component of the National Institutes of Health (NIH). This means that the University of Iowa is receiving payments from the NIH to support the activities that are required to conduct the study, which the university uses to pay the researchers and pay for all aspects of the study. No one on the research team will receive a direct payment or increase in salary from NIH for conducting this study.

### **WHAT ABOUT CONFIDENTIALITY?**

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other entities, including federal government regulatory agencies or the University of Iowa Institutional Review Board (a committee that reviews and approves research studies), may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

As mentioned previously, data and other information collected for **this research are covered by a Certificate of Confidentiality from the National Institutes of Health (NIH)**. This Certificate ensures the ability of all persons working on this study to protect the privacy of participants and their data.

- In essence, the Certificate of Confidentiality authorizes the researchers to protect the privacy of individuals who are the subject of research by withholding from all persons not connected with the conduct of the research the names or other identifying characteristics of such individuals. The researchers may not be compelled in any Federal, State, local, civil, criminal, administrative, legislative, or other proceedings to identify such individuals, as provided in Section 301(d) of the Public Health Service Act, 42 U.S.C. 241(d), "Protection of privacy of individuals who are research subjects."
- The Certificate cannot be used to refuse a request for information from personnel of the United States federal government agency sponsoring the project (the NIH) that is needed for auditing or program evaluation by the NIH, or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). The Certificate of Confidentiality does not prevent you from voluntarily releasing information about your involvement in this research.

Protecting your privacy. The research team is committed to respecting and protecting your privacy and keeping your personal information confidential. We will make every effort to protect your information to the extent allowed by law. Your records will be given a code number and will not contain your name or other information that could identify you. The code number that connects your name to your information will be kept in a password-protected electronic file in a locked office within the lab, which is accessible only by magnetic key card and only by authorized personnel.

When the results of this research are shared, such as in a scientific journal, we will remove all identifying information so it will not be possible to identify any individuals. Your information will be kept as secure as possible to prevent your identity from being disclosed.

### **Data Storage for Future Use**

As part of this study, we will obtain questionnaire, behavioral, and brain activity data from you. We would like to continue to use your data in the future, after the study is over, for additional data analyses that could inform new discoveries. Any data we keep after the study is over will be de-identified, meaning information that identifies the data as having come from you will be stripped from the dataset.

If you agree now to future use of your data but decide in the future that you would like to have it removed from future research, you should contact Dr. Bruce Bartholow: (573) 289-4605. However, if some research with your data has already been completed, the information from that research may still be used.

*Do you agree to allow the researchers to store your data for future use after this study is completed?*

YES ☐

NO ☐

We might wish to contact you again in the future, after this study is over, to ask you to participate in another study. You can choose whether to allow us (or other researchers) to contact you again after this study is over. You also will have the right to decide whether to participate in any future research, regardless of what you decide about participating in this study. You can also change your decision about future

contact at any time; this decision will not affect your participation in this study or the compensation you receive for participating.

*Do you agree to allow the researchers to contact you and ask you to participate in future studies?*

YES ☐

NO ☐

We are required to submit some parts of the data from this study to the National Institute on Alcohol Abuse and Alcoholism Data Archive (NIAAA<sub>DA</sub>) at the National Institutes of Health (NIH). NIAAA<sub>DA</sub> is a large database where de-identified study data from many NIAAA-sponsored studies is stored and managed. De-identified study data means that **all personal information about you (such as name, address, birthdate, and phone number) is removed and replaced with a code number**. Sharing de-identified study data helps researchers learn new things about alcohol problems more quickly than before.

During and after the study, the researchers will send your de-identified study data to the NIAAA<sub>DA</sub>. Other researchers across the world can then request access to the de-identified study data for their research. Every researcher (and institutions to which they belong) who requests the de-identified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce any risks to your privacy. Sharing your study data does have some risks, although these risks rarely occur. The study data could be accidentally shared with an unauthorized person who may attempt to learn your identity.

### **IS BEING IN THIS STUDY VOLUNTARY?**

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

### **What if I Decide to Drop Out of the Study?**

You are free to drop out of the study at any time. You will not be penalized or lose any benefits for which you otherwise qualify. You will still be compensated for any parts of the study you have already completed at that time.

### **Will I Receive New Information About the Study while Participating?**

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we will promptly share that information with you.

### **WHAT IF I AM INJURED AS A RESULT OF PARTICIPATING IN THIS STUDY?**

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- No compensation for treatment of research-related illness or injury is available from the University of Iowa unless it is proven to be the direct result of negligence by a University of Iowa employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

## **WHAT IF I HAVE QUESTIONS?**

We encourage you to ask questions. If you have any questions about the research study itself, please contact Ms. Nicole Schlegel by email (CARD-study@uiowa.edu), or contact Dr. Bruce Bartholow by email ([bruce-bartholow@uiowa.edu](mailto:bruce-bartholow@uiowa.edu)) or office phone (319-335-1333).

If you experience a research-related injury, please contact Dr. Bruce Bartholow (573-289-4605).

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail [irb@uiowa.edu](mailto:irb@uiowa.edu). General information about being a research subject can be found by clicking “Info for Public” on the Human Subjects Office web site, <http://hso.research.uiowa.edu/>. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

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This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): \_\_\_\_\_

\_\_\_\_\_  
(Signature of Subject)

\_\_\_\_\_  
(Date)

## **Statement of Person Who Obtained Consent**

I have discussed the above points with the subject or, where appropriate, with the subject’s legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

\_\_\_\_\_  
(Signature of Person who Obtained Consent)

\_\_\_\_\_  
(Date)