Alcohol Labeling Study

NCT number NCT06835920
Document Date 03/28/2025

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants for Randomized Controlled Trial

Consent Form Version Date: March 28, 2025
IRB Study # 23-1218
Title of Study: Developing New Labels
Principal Investigator: Marissa Hall
Principal Investigator Department: Health Behavior
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Funding Source and/or Sponsor: NIH National Institute on Alcohol Abuse and Alcoholism

Concise Summary. We would like to invite you to take part in a research study to understand the effects of putting labels on alcoholic beverage containers. This study is open to adults ages 21 and over who drink alcohol.

You will participate in this study for about 3 weeks. During the study, you will make 3 in-person visits to the study site, each of which will last approximately 30 minutes. For each in-person visit, you will bring 8 days' worth of unopened alcohol with you to the study site. We will apply labels to these containers, and you will take a short computer survey. There are two groups of labels that will be placed on alcohol, and you will have equal chance of being placed in either group (like flipping a coin). A week after your third in-person visit, you will complete a final online survey sent via email that can be completed anywhere. It should take about 20 minutes. In addition to the three study site visits and online survey, you will be asked to complete daily, one-minute surveys sent to your phone. You will be paid in e-gift cards after each study site visit.

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study. Potential risks to participating in this study include (1) discomfort while answering the surveys and (2) loss of privacy resulting from accidental disclosure of responses to survey questions. However, we have taken steps to limit the probability of these risks occurring.

If you are interested in learning more about this study, please continue reading below.

What are some general things you should know about research studies?
You are being asked to take part in a voluntary research study. You may choose not to participate, or you may withdraw from the study, for any reason, without penalty. Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be offered a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to understand what people think about alcohol. You are being asked to be in the study because you are an adult aged 21 or older who consumes alcohol.

How many people will take part in this study?
A total of approximately 800 people will participate in this research study.

How long will your part in this study last?
Your participation in this study will consist of three visits to our study offices in North Carolina. Each visit will last approximately 30 minutes. You will also complete one 20-minute online survey at home. You will also be asked to complete daily surveys sent to your phone. The daily surveys will take approximately one minute each.

In the rare case that your survey data do not save, we may contact you by phone to collect any information we are missing.

Are there any reasons you should not be in this study?
You should not be in this study if you are currently pregnant. You should not be in this study if you do not own a cell phone that can send and receive text messages. You should not participate in this study if you have alcohol use disorder or prefer not to be exposed to alcohol.

What will happen if you take part in the study?
Alcohol Container Labeling: During the three in-person visits, you will be asked to bring the amount of unopened alcoholic beverages you plan to drink over the next 8 days with you to each study site visit. Research staff will then put labels on your alcohol containers.
Study Site Visit Surveys: While your alcoholic containers are being labeled, you will be asked to take a survey on a computer. You may choose to skip questions in the survey for any reason.
At-home Survey: About 1 week after your last in-person visit, you will complete 1 online survey sent to you via email. You do not need to come in person for this.
Daily Surveys: Between study visits, you will respond to daily surveys sent via text. These should take you only 1 minute per day to complete.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study.

What are the possible risks or discomforts involved from being in this study?
Two potential risks to participating in this study include (1) discomfort while answering the surveys and (2) loss of privacy resulting from accidental disclosure of responses to survey questions. Since alcohol is a legally regulated substance, you are expected to follow all local laws while participating in the study. This includes opening, transporting, and consuming alcohol only where it is legally allowed. There may be uncommon or previously unknown risks. You should report any problems to the researcher.

Not only are these risks small, but the consequences of a rare accidental disclosure would also be small because we take precautions to protect participant data. Once all data is collected, we will store personally identifying information separately from your data. If these data were disclosed, they would not affect insurability, social standing, or employment. In this way, data collected by the study do not pose any risk greater than what participants encounter in their daily life.

How will information about you be protected?
Your responses to survey questions will be confidential. We will assign you a unique numerical identifier to be used on all study documents (e.g., completed surveys). We will shred any paper copies of your contact information and maintain an electronic version of your name, identifier, and phone number on a secure, password-protected server that can only be accessed by study personnel. If you indicated that you were interested in hearing about future research studies, we will maintain your contact information indefinitely, separate from any other study data.
Participants will not be identified in any report or publication about this study. We may use de-identified data from this study in future research without additional consent. A de-identified version of the dataset may be made available publicly online.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

This study requires your willingness to send and receive text messages for 21 days throughout the study. We may use texts to send appointment reminders and will send the 1-minute daily survey through a platform called Mosio. The daily survey will show up on your phone as a text message. While Mosio will keep your text responses password protected, any information sent via text will be stored on your personal cell phone (in your texts). This means there is a risk of someone else seeing the information you send. You may reduce this risk by using a password on your phone or deleting text messages after you have responded.

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many NIH studies are stored and managed. Sharing your deidentified study data helps researchers learn new and important things about brain science more quickly than before.

Deidentified 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. The study researchers will have to collect your personal information from you in order to make that code number. The code number cannot be used to identify you. The study researchers will never send your personal information to NDA.

It is possible that you will participate in more than one study that sends data to NDA. NDA can connect your data from different studies by matching the code number on your deidentified data from each study. This data matching helps researchers who use NDA data to count you only one time. It also helps researchers who use NDA to better understand your health and behavior without knowing who you are.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NDA. Other researchers across the world can then request your deidentified study data for different research projects. Every researcher (and the institution to which they belong) who requests your deidentified 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 risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about brain science and how to help others who have problems with brain science. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to NDA. You can still participate in this research study even if you decide that you do not want your data to be added to NDA. If you know now that you do not want your data in NDA, please tell the study researcher before leaving the clinic today. If you decide any time after today that you do not want your data to be added to NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, it is available on-line at http://nda.nih.gov.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

What is a Certificate of Confidentiality?
This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes 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 will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

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 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.

Will you receive anything for being in this study?
You will receive e-gift card credit after each study visit. You can earn $60 for each in-person visit, $20 per week for completing the 1-minute daily surveys, and $35 for completing the final online survey. The most possible you can receive is $275 total over the 3-week study period. We will distribute the e-gift card incentives on a weekly basis at the end of each study site visit, so if you miss one, you will not be compensated for that visit. We will send the incentives for your last week of participation within 1 week of your final at-home survey. You will pick which e-gift cards you want from hundreds of options.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. You will receive study incentives only for the activities you complete. The investigators also have the right to stop your participation at any time. This could be because the entire study has been stopped. If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained; however, no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will it cost you anything to be in this study?
You are expected to bring in the alcohol you would normally buy and drink. All alcohol must be unopened, so you may need to purchase alcohol if what you typically drink is already open. Additionally, you may have to pay for transportation to the study office. You will not be reimbursed for this cost. Parking at the study offices is free of charge.

Who is sponsoring this study?
This research is funded by NIH National Institute on Alcohol Abuse and Alcoholism. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:
I have read the information provided above. I have asked all the questions I have at this time. By typing my name and signing below, I understand this is a representation of my legal signature, and I voluntarily agree to participate in this research study.

_____
Signature of Research Participant

_____
Printed Name of Research Participant

_____
Signature of Research Team Member Obtaining Consent

_____
Printed Name of Research Team Member Obtaining Consent