

Informed Consent

Alcohol Metabolism and Disease Risk in Asians

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INFORMED CONSENT FOR RESEARCH

Study Title: Asian College Student Personalized Feedback Study

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Department: Psychology

INTRODUCTION

We invite you to take part in a research study. Please take as much time as you need to read the consent form. You may want to discuss it with your family, friends, or your personal doctor. If you find any of the language difficult to understand, please ask questions. If you decide to participate, you will be asked to sign this form. A copy of the signed form will be provided to you for your records.

PURPOSE

The purpose of this study is to understand your response to participating in a brief online personalized feedback session that may be related to being a USC college student, being of Asian heritage, bodily responses to drinking alcohol, health risks of drinking alcohol, or a combination of factors. You are invited as a possible participant because you are a USC undergraduate student who self-identifies as Asian, are between 17-25 years old, and expect to attend USC for the next year. About 360 participants will take part in the study. This research is being funded by the National Institute on Alcohol Abuse and Alcoholism.

PROCEDURES

All procedures are done solely for research. If you decide to take part, this is what will happen. Your total length of participation will last about 15 months.

1. Initial Assessment. This will take about 1 hour. You will be asked to:

- Complete surveys on your personal and familial demographics and medical history relevant to participation and your behavior including substance use, your thoughts and feelings, and aspects of your personality. This includes questions about the kind of person you think you are.
- Provide saliva for DNA analysis. This means you are being asked to participate in genetic testing. A genetic counselor may be available to you to discuss the results of this testing.

2. Online Survey, Personalized Feedback, and Post-Feedback Survey session. This session will last about 1 hour. For this session, you will be asked to:

- Complete an online survey on your behavior including substance use and your thoughts and feelings over the past 90 days.
- Participate in a brief online feedback session designed to provide you with personalized information related to your being a USC college student, being of Asian heritage, or a combination of factors. You will be randomly assigned (by a procedure like rolling a die) to the feedback session. You may receive feedback on some of your genes as part of this personalized feedback session. You will not receive additional information about the feedback session(s) you are not randomly assigned to while you are in the study.

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- Complete an online survey about the feedback session you received.

3. Online Surveys The survey will take about 15 minutes to complete. You will be asked to complete it 1 month after the personalized feedback session and three more times every 3 months after the personalized feedback session. In each of these four surveys, you will be asked to:

- Complete an online survey on your behavior and feelings over the past 90 days.

4. End of Study Evaluation and Survey. The survey will take about 10 minutes to complete. You will be asked to complete an evaluation and survey about the study.

5. Feedback After Study Completion: If you complete the study, at the end of your participation you will have the opportunity to view the brief online personalized feedback session(s) you did not receive during the study. You will make this selection during the final feedback survey of your participation. You also will have the opportunity to meet with study investigators in a group session to ask any questions you might have.

6. Optional Contact After Study Completion: Professor Luczak or her staff may contact you once or twice a year over the next 5 to 10 years by mail, email, telephone, online, or in person to tell you about future research participation opportunities. To stay in contact, you must give permission for the research team to re-contact you or any persons that you designate or to conduct online searches to update our tracking records. You may also choose not to be re-contacted. At the end of this consent form, you will check a box to indicate your decision.

7. Optional Submission of Data 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. It also helps researchers who use NDA to better understand your health and behavior without knowing who you are. 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.

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.

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.

If you would like more information about NDA, it is available on-line at <http://nda.nih.gov>.

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You can still participate in this research study even if you decide that you do not want your data to be added to NDA. At the end of this consent form, you will check a box to indicate your decision if you want or do not want your study data to be added to NDA.

RISKS AND DISCOMFORTS

Surveys/Questionnaires/Interviews: Some of the questions may make you feel uneasy or embarrassed. You can choose to skip or stop answering any questions you don't want to.

Breach of Confidentiality: There is a risk that people who are not connected with this study will learn your identity or your personal information.

Genetic Testing: A federal law, called the Genetic Information Nondiscrimination Act (GINA) 2008, that protects people from genetic discrimination in health insurance and employment. Genetic discrimination is the misuse of genetic information.

It is against the law for health insurers to request, require, or use genetic information to make decisions about your eligibility for health insurance or your health insurance premium.

It is against the law for employers to use genetic information to make decisions about hiring, firing, promotion or pay; or to limit, segregate classify or otherwise mistreat an employee. It is also illegal for an employer to request, require, or purchase genetic information.

Sometimes health insurers need genetic information to make decisions about paying for certain tests or treatments. It is legal for them to ask for this information. However, once they have it they cannot use it to discriminate against you in the ways described above.

Some people may find it upsetting to learn that they have certain mutations or errors in genes that could lead to future health problems for themselves or their children.

Unforeseen Risks: There may be other risks that are not known at this time.

BENEFITS

There may be no direct benefits to you from taking part in this study. A potential benefit to you may include receiving feedback on factors that are personal to you that may affect your risk for some diseases.

A potential to benefit to society is that this research could help us understand how to inform individuals about their risk for disease and ways to reduce this risk. This could potentially help to reduce preventable disease.

If you agree to have your data included in NDA today, 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.

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PRIVACY/CONFIDENTIALITY

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who are required to review this information. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name.

The University of Southern California's Institutional Review Board (IRB) may review your records. Organizations that may also inspect and copy your information include the National Institute on Alcohol Abuse and Alcoholism as the funding agency.

Your data will be stored in either locked filing cabinets or computers/servers protected with access codes known only to the research staff. Data will be entered and stored using identification numbers and not names. Data from the online screening and surveys will be linked to the laboratory data. The saliva specimen you provide will be analyzed by the USC Norris Molecular Genomics Core Facility and will be sent to them and stored using identification numbers and not names.

Your information or samples that are collected as part of this research may be used or distributed for future research studies without your additional informed consent. Any information that identifies you (such as your name) will be removed from your private information or samples before being shared with others.

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

The investigators are required to report certain cases with the potential of serious harm to you, or others, such as suicidality or child abuse, to the appropriate authorities.

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. Some examples are 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.

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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.

If you agree to have your data included in NDA, 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.

ALTERNATIVES TO PARTICIPATION

An alternative would be to not participate in this study.

PAYMENT/COMPENSATION FOR PARTICIPATION

You may receive up to \$200 compensation in gift cards for participating in the study:

Initial Assessment	\$50
Online Survey, Personalized Feedback, and Post-Feedback Survey Session	\$50
1-month and 3-month Online Surveys including final study evaluation (\$25 each)	\$100

If you only complete some portion of the study, you will be paid for that portion. For example, if you complete half of the initial session, you will receive \$25 compensation for that session. However, if you do not complete the initial session, you may not be eligible to continue in the study.

You will receive the gift card for the initial assessment by mail or email once all items have been received. You will be sent additional gift cards after each online surveys by mail or email, or the gift card you already have will have money added to it.

COST

There are no costs related to participation in this study.

INJURY

If you think you have been hurt by taking part in this study, tell the study investigator immediately. There are no plans to offer any type of payment for injury. However, by signing this form you have not given up any of your legal rights.

VOLUNTARY PARTICIPATION

It is your choice whether to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

If you stop being in the research, already collected data may not be removed from the study database. No new information or samples will be collected about you or from you by the study team without your permission. The study site may still, after your withdrawal, need to report any safety event that you may have experienced due to your participation to all entities involved in

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the study. Your personal information, including any identifiable information, that has already been collected up to the time of your withdrawal will be kept and used to guarantee the integrity of the study, to determine the safety effects, and to satisfy any legal or regulatory requirements.

For NDA, if you decide any time after today that you do not want your data to be added to NDA, contact 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.

PARTICIPANT TERMINATION

You may be removed from this study without your consent for any of the following reasons: you do not follow the study investigator's instructions, you do not complete the initial assessment, or at the discretion of the study investigator.

CONTACT INFORMATION

If you have any questions or concerns about the research, please feel free to contact Susan Luczak, Ph.D., (Luczak@usc.edu) Principal Investigator, Department of Psychology, SGM 501, 3620 S McClintock Ave., Los Angeles, CA 90089, (213) 740-2203.

This research has been reviewed by the USC Institutional Review Board (IRB). The IRB is a research review board that reviews and monitors research studies to protect the rights and welfare of research participants. Contact the IRB if you have questions about your rights as a research participant or you have complaints about the research. You may contact the IRB at (323) 442-0114 or by email at irb@usc.edu.

STATEMENT OF CONSENT

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions have been answered. By signing this form, I am agreeing to take part in this study.

Please check one of the following choices:

- ☐ I agree to be contacted in the future.
- ☐ I do NOT agree to be contacted in the future.

Please check one of the following choices:

- ☐ I agree to include my data in NDA.
- ☐ I do NOT agree to include my data in NDA.

Name of Research Participant

Signature

Date Signed
(and Time*)

MINOR/YOUTH PARTICIPANT ASSENT (*AGE 17 YEARS*)

If as a child you agree to participate, sign here. If you continue to participate in the study when you turn 18 years old, you will be asked to consent to participate as an adult and to sign this form on the line above.

Name of Child	Child's Signature	Date Signed (and Time*)

Person Obtaining Consent

I have personally explained the research to the participant using non-technical language. I have answered all the participant's questions. I believe that the participant understands the information described in this informed consent and freely consents to participate.

Name of Person Obtaining Informed Consent	Signature	Date Signed (and Time*)