

CONSENT FORM

Saliva Sample Collection, Genotyping, and Matching of DNA Sample with Archival Survey Data **The University of Texas at Austin**

You are being asked to participate in a research study. This form provides you with information about the study. The Principal Investigator (the person in charge of this research) or her representative is available to describe this study to you and answer all of your questions. Please read the information below and contact us with questions about anything you don't understand before deciding whether or not to take part. Your participation is entirely voluntary and you can refuse to participate without penalty or loss of benefits to which you are otherwise entitled.

Title of Research Study: Genes and New Experiences Study (Also "Mechanisms of Behavior Change")

Principal Investigator, UT affiliation, and Telephone Number:

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Funding source: National Institute on Alcohol Abuse and Alcoholism (NIAAA)

What is the purpose of this study? The purpose of this study is to better understand the relationship between gene polymorphisms (natural genetic differences between people) and substance use and other behavioral risks, including sexual behavior, aggression, drinking and driving, and illegal acts among current and former college students. We will recruit approximately 1,060 participants who have previously participated in "The UT Experience!" research study.

What will be done if you take part in this research study? This study involves three parts, and we will ask for your consent for each part.

1. Salivary Sample Collection and Genotyping. In this package is a consent form and an Oragene-DNA® salivary DNA self-collection kit. You will use this kit in order to provide a small saliva sample. In order to provide the saliva sample, you will spit into the clear plastic tube until the collected saliva reaches the fill line (2 mL). You will mail the sample, along with your signed consent form, back to the researchers at the University of Texas at Austin using the enclosed postage-paid envelope. Alternatively, you may provide written consent and the saliva sample in our laboratory, or return the signed consent form and sample in-person to the SAHARA lab at UT. If you prefer to provide a saliva sample in-person at the lab, please call the study investigators at the telephone number listed above, in order to schedule an appointment. Whether done at home or in the lab, providing a saliva sample should take no more than 10 minutes.

Once we collect your saliva sample (in person or via mail), we will store it in a freezer, then send it to the Institute of Behavioral Genetics in Colorado for extraction and analysis of the DNA contained in the saliva. We will genotype your DNA for 5 genes: GABRA2, SLC6A4, DRD4, OPRM1, and CHRM2. In addition, we will genotype your DNA for polymorphisms (i.e., genetic sites that differ between people) that are very different between people of different races and ethnicities. This will allow us to control, in our analyses, for genetic "ancestry."

2. Retention of DNA Sample for Future Genotyping. Given that genetics research is developing at a very rapid pace, and new discoveries are made almost every day, we will keep your genetic information indefinitely. We may use genotype your samples for genes other than those of interest in the current study (the genes listed above), including genes that may not have yet been identified. Please be assured that all of your identifying information will be removed from your saliva samples. Master files containing your demographic information (e.g., age, sex, name, and identification number) will be kept in a secure location at the University of Texas at Austin that is separate from your saliva samples. This master file containing your identifying information will be destroyed at the end of this study. Only investigators involved in the study and their research staff will have access to identifying information. While we may share the results

of our genetic analyses with other study investigators, we will never transfer ownership of your saliva/DNA samples to other parties.

3. Archival data collected from the UT Experience study will be linked to the analysis of the saliva sample that will be collected as part of the current study.

What are the possible discomforts and risks? Because we will be collecting personal information, a potential risk is loss of privacy. For instance, one potential breach of confidentiality could involve genetic information that is linked to your personal information. The risk of breach of confidentiality will be minimized by ensuring that all information obtained during the study remains confidential and will be used solely for research purposes. All research staff will be closely supervised, trained, and reminded of the need to keep all information confidential. Additional measures will be taken to protect your confidentiality. All archival data will be stored on secure, encrypted, password-protected servers, to which only trained project staff have access. Your saliva sample will be kept in a separate secure location, identified only by a number, and separate from other identifying information you have provided (e.g., name, address). Finally, your name will never be associated with publications or presentations based upon this project. If you wish to discuss these or any other risks you may experience, you may contact the Principal Investigator listed on the top of this form. In the unlikely event you were to experience significant emotional distress as a result of your participation, please contact the Principal Investigator at the number listed above. The Principal Investigator or a senior member of the research staff will usually return your call within 24 hours on a weekday. They can provide the names and telephone numbers of agencies in your area that may alleviate your concerns or distress. If you require more immediate assistance, please call the National Crisis Hotline at 1-800-273-TALK for local referrals.

What are the possible benefits to you or to others? There are no direct benefits to you, but the potential benefits to other college students and society as a whole include an increased understanding of specific genetic factors associated with substance use and other behavioral risks. Such knowledge may ultimately lead to the development of more effective prevention programs targeting substance use and other behavioral risks.

If you choose to take part in this study, will it cost you anything? It will cost you nothing but your time to participate in this research.

Will you receive compensation for your participation in this study? After we receive your saliva sample, you will be compensated \$35. *If you also previously* completed a survey, you will receive a bonus of \$10. You can pick up your compensation in the form of a check at the Twins and Genetics Lab in the Psychology Department at the University of Texas or we can mail it to you.

What if you are injured because of the study? There are no physical risks involved in this research.

If you do not want to take part in this study, what other options are available to you?

Participation in this study is entirely voluntary. You are free to refuse to be in the study, and your refusal will not influence your current or future relationship with The University of Texas at Austin.

How can you withdraw from this research study and who should you call if you have questions? If you wish to stop your participation in this research study for any reason, you may contact Kim Fromme, Ph.D. (Principal Investigator) or senior research staff at (512) 471-7385 or by email: utgenes@utexas.edu. You are free to withdraw your consent and stop participation in this research study at any time without penalty or loss of benefits for which you may be entitled. Throughout the study, the researchers will notify you of new information that may become available and that might affect your decision to remain in the study.

In addition, if you have questions about your rights as a research participant, complaints, concerns, or questions about the research please contact The University of Texas at Austin Institutional Review Board for the Protection of Human Subjects at the Office of Research Support at (512) 471-8871 or email: orsc@uts.cc.utexas.edu.

How will your privacy and the confidentiality of your research records be protected?

As mentioned above, all identifying information (e.g. age, name, sex, etc.) will be kept separate from all the information you provide, including your DNA sample and previous responses on “The UT Experience!” surveys. We have also obtained a Certificate of Confidentiality from the National Institutes of Health, which further protects the security of our data from possible subpoena. Lastly, the Department of Health and Human Services (DHHS) may see your information if it audits us, though this implies neither approval nor disapproval by DHHS.

If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

Will the researchers benefit from your participation in this study? The researchers will not benefit from your participation.

By checking the boxes below, labeled “I agree to participate,” you acknowledge that you have been informed about this study’s purpose, procedures, possible benefits and risks. This also acknowledges that you have been given the opportunity to ask questions before you consent, and you have been told that you can ask other questions at any time. You voluntarily agree to participate in this study.

I agree to provide a saliva sample, which will be genotyped for five genes (GABRA2, SLC6A4, DRD4, OPRM1, and CHRM2), plus genes that will indicate my ethnic ancestry.

I agree to having my DNA sample matched to data from the previous “The UT Experience!” surveys.

I agree to having my saliva/DNA sample retained by the study investigators, to be genotyped in the future for research purposes that have not yet been determined.

By checking any or all of the boxes above, and signing below, you are providing consent to participate, but you are not waiving any of your legal rights. A copy of this consent form that has been signed by the Principal Investigator will be sent to you with the saliva collection kit.

Printed Name of Subject

Date

Signature of Subject

Date

Signature of Principal Investigator

Date