

Study Information

The ENGAGE-D Study of Diversity, Genetics, and Alcohol

IRB #: HM20007705

INVESTIGATOR: Dr. Karen Chartier
Virginia Commonwealth University

We thank you once again for participating in The ENGAGE-D Study. The overall purpose of this research is to understand what factors influence how much alcohol people drink. **We asked you to participate because you took part in a phone survey for the Public Health Institute on alcohol and health about a year ago.** At that time, you gave us permission to contact you again. Our invitation does *not* imply that you or your family members drink too much alcohol, or that you are at risk for alcohol problems.

The ENGAGE-D Study includes 2 parts. (1) You already completed a brief phone survey and agreed to receive a mailed packet for collecting a sample of your saliva. (2) We are now asking you to mail your saliva (or spit) sample to the Virginia Commonwealth University (VCU) Genetics Lab. You are free to choose whether or not to participate in the saliva collection part of this study.

Alcohol problems are due to the influence of genes and other factors, like whether a community store near you sells alcohol, or whether family and friends drink. We would like you to provide a saliva sample so that we can study how DNA influences alcohol use. Your saliva contains DNA from cells in your mouth. DNA contains the genes you inherit from your birth parents. Differences in genes may be related to the differences we see in how much alcohol people drink.

We plan to use your saliva sample to examine genes we think are related to alcohol use and health. If you agree to take part, you are giving us permission to: (1) get and store a small saliva sample from you; (2) read your DNA and connect the information to answers from both your surveys; and (3) share your DNA information and survey answers, **without your name, address, and date of birth**, with qualified researchers for future studies about alcohol and health. Because science advances so quickly, we may apply new techniques that may emerge in the future. Our goal will always be to understand how genes and other factors influence alcohol use and health.

We mailed \$5 cash in the packet to thank you for taking the time to complete the phone survey and agreeing to receive the kit. **You will get a \$20 gift code to Amazon.com for the time and effort to collect your saliva sample and to mail it to the lab.** You will receive the code by email or over the phone, whichever you asked for at the end of the phone survey. There is no cost to you; a return envelope with prepaid postage is included in the packet. It will take about 5 minutes to provide the sample, plus time to mail the sample back to us. After we receive your sample, we will contact you with your gift code. We also may contact you and ask you to provide a second sample. This could happen if there isn't enough DNA in the sample you send or if there was a problem with the container.

There is no physical risk to participating in this study. The collection of saliva is painless. Giving a sample involves filling a plastic tube with a small amount of saliva.

The tube to collect your sample is labeled with a code number, not with your name or any other identifying information about you. The answers to your phone surveys have also been given code numbers. These codes will be used to match your DNA information and survey answers. This is done so that researchers can study your DNA and responses, but not have access to your name or address. Your DNA saliva sample will be stored using a code number at the VCU Genetics Lab. It will be stored until the study is completed or we can no longer use the DNA, because DNA can be difficult to store or may get used up. If funded, we will genotype the samples collected during this study at a facility recommended by the National Institutes of Health.

There is a small risk that your identity could be linked to your DNA or data. **However, we take many precautions to keep all information we collect strictly confidential.** Again, we will use code numbers instead of names. Also, your sample will be kept in a secure and locked freezer at the VCU Genetics Lab. The people who work at the lab will not have access to any identifying information about you. They will not know who you are. The identifying information you give us is kept separate from your saliva sample on secure and password protected computers. The researchers who analyze the data will not know your name or other identifying information about you. You will not be identified in any research report, publication, or presentation that may result from this study.

We are in the process of obtaining a Certificate of Confidentiality from the Federal Government as another precaution. This Certificate's protection applies to your DNA sample and survey data. The Certificate protects us from having to reveal your identity or the information you give us, even under court order. Under certain circumstances, you could still give us written permission to release this information, however. This Certificate will help us protect the confidentiality of your data. Additional details about the protections and limitations of the Certificate of Confidentiality can be found at <http://grants.nih.gov/grants/policy/coc/>. Authorized federal regulators whose job it is to ensure that the rights of research participants are protected might review your study information.

Genetics research often needs DNA from tens or hundreds of thousands of individuals. We may share your data with a large repository, like dbGaP (<https://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/about.html>). A repository is a database of information for sharing with the research community. **We will not share any identifying information about you.** All data would be stored using random numbers unconnected to the code numbers used in this study. Qualified researchers must apply for access and receive approval to use these repositories. This type of future study may provide additional information that will be helpful in understanding alcohol use and health.

There is no direct benefit to you for participating in this study. **Data are being collected for research purposes.** The technology we use is for genetic research only. It is not the same as what is used for genetic testing you would receive at a hospital or doctor's office. We know that alcohol problems are not caused by any single gene, so we are unlikely to identify if your genes increase or decrease your risk of having any disease or genetic disorders. Because of this and because your data will be de-identified to protect your privacy, we will not provide any results of genetic testing to you. Our hope is that this study will allow us to better understand how normally occurring differences in people's DNA contribute to differences in alcohol use. We will share information with you about the study on the ENGAGE-D website, <http://arg.org/engaged/>.

Your participation in this study is voluntary. You are free to stop participating in this study at any time. You should call the investigator in charge of the study if you decide to do this. There are some limitations to withdrawal. If you choose to withdraw, your DNA sample and associated genetic data will be destroyed. Your survey responses will be kept for analysis. Five years after the study ends, we will destroy all documents that include your name and other identifying information to protect your confidentiality. After this point, we will no longer be able to connect you to your data.

If you have any questions about this study, contact the ENGAGE-D study team at 1-844-604-4164, or by email at engaged@icfsurveysupport.com. You can also contact the Principal Investigator:

Dr. Karen G. Chartier
Virginia Commonwealth University School of Social Work
1000 Floyd Avenue, P.O. Box 842027
Richmond, Virginia 23284-2027

Dr. Chartier's email address is kgchartier@vcu.edu and phone number is (804) 828-2865.

If you have any questions about your rights in this study you may contact the **Office of Research at Virginia Commonwealth University at (804) 827-2157**. Please call this number if you cannot reach the ENGAGE-D study team or if you wish to talk to someone else.