

Spit for Science: The VCU Student Survey

IRB #: HM13352

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Consent Form for Collection of a DNA (Saliva) Sample

This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand. You may request or download an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

We thank you once again for your participation in Spit for Science: The VCU Student Survey. As a reminder, your participation in this research is voluntary. You are free to choose whether or not you want to participate in this portion of the project. Refusal to participate or withdrawal from participation will involve no penalty or loss of benefits to which you are otherwise entitled.

Purpose & Background: The overall purpose of this research is to understand what factors contribute to the use of alcohol and other substances, and emotional health, across the college years and beyond. We know that most behavioral outcomes are the result of both environmental and genetic factors. We would like for you to provide a saliva sample, so that we can study how variation in DNA influences alcohol use, use of other substances, and emotional health. For example, this will allow us to understand which genetic variants influence how frequently people drink, or influence why some people are more likely to get depressed than others when they experience a stressful life event. Because genetic science advances so quickly, the specific genetic techniques we will use to study DNA may change over the course of this project. Accordingly, we plan to use the samples to examine genetic variation that is believed today to be related to outcomes of interest in the Spit for Science project, and to apply new genetic techniques that may emerge in the future. Our scientific goal will remain to understand how variation in DNA interacts with environmental factors to contribute to the use of alcohol and other substances, and emotional health.

Your Involvement: Giving a DNA sample involves filling a plastic tube with a small amount of saliva. *The procedure should take less than 10 minutes.* Samples are labeled with a code number, not with your name or any other identifying information about you. This is the same code number that is attached to your survey and all data obtained from the University and linked to the Spit for Science project, so that we are able to connect the DNA samples with this information without ever having to connect them to any identifying information about you. These coded samples will be stored at a research laboratory at VCU until the study is terminated or the DNA is no longer viable for study.

Compensation: You will receive a \$20 e-gift card for your time and effort. Total payments within one calendar year that exceed \$600 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to track these payments using your V number or social security number (optional) and/or contact information. If provided, your social security number will be kept confidential and will only be used to process payment.

Risks & Discomforts: Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you. If known to employers or insurance companies, the results of genetic tests might affect a person's ability to obtain a job or health or life insurance. If this information were released, it could be misused. Such misuse could be distressing, and it could cause you or your family members to have difficulty obtaining insurance coverage and/or a job. A federal law called the Genetic Information Nondiscrimination Act (GINA) makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, this legal protection still may not keep someone from trying to discriminate against you in this way. However, we take many precautions to keep all information we collect from you strictly confidential.

Protecting Confidentiality Privacy: The DNA is stored with code numbers, without names, and kept in a secure location. The code numbers and associated genetic data are stored in password-protected computer files. **The individuals who work with your DNA will not have access to any identifying information about you.** They will not even know who you are. The code number will be used to match genetic information with survey information and in all analysis files. The investigators who oversee the analyses for this project and who work with the DNA and survey response files will not have access to your names or other identifying information about you. Research analysis will be done without names attached to data, and data will only be reported in aggregate form, so individuals will not be identifiable from any research report. In the future, your de-identified sample could be used for other research studies by this study team or another researcher without asking you for additional consent. Your identity will not be revealed in any publication that may result from this study. Certain organizations are in charge of making sure researchers do what they say they will do. Some of these organizations are part of VCU, VCU Health System, and the U.S. Department of Health and Human Services. When people from these organizations review the research, they may see or copy information that the researcher collected. It is unlikely these people or organizations will know who the information is about because the researcher stores your personal information (like name and email address) separate from your survey responses. Additionally, a data and safety-monitoring plan has also been established.

Additional Protections: As another precaution, all of the information collected in this research is covered by a Certificate of Confidentiality from the National Institutes of Health. This Certificate's protection applies to the DNA data and the other data collected as part of this project, such as the survey responses. The researchers with this Certificate 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 action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the organization funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

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 you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

In order to further protect the confidentiality of all participants, we cannot provide individual feedback about the DNA analysis to anyone participating in the study. This would not be possible, since the DNA data will never be linked to the names or other identifying information about the participants.

This study will use your samples to sequence all or part of your DNA. Deoxyribonucleic acid (DNA) is the "blueprint" or "recipe" that gives the body's cells instructions on how to do their jobs. Scientists can use a test called whole genome sequencing to determine the order of all or part of the molecules that make up your DNA, like reading all the letters in a book. Sequencing is usually done to look for changes in the molecules of DNA that may cause health problems.

Because advances in genetics often require DNA from tens or hundreds of thousands of individuals, the National Institutes of Health (NIH) asks scientists to work together and deposit de-identified genetic data (data labeled with code numbers that contain no identifying information) into a national database. The goal of this is to create a national resource to help advance science and medicine. We will deposit DNA data from the Spit for Science project, along with outcome data (such as the survey responses), into this national database. All of the data that go into the database are stored there using random numbers. **No identifying information about you would be released by the researchers at VCU or be included in the database.** This database is part of the Genome Wide Association Studies (GWAS) sponsored by the NIH. Anyone who wants to work with this resource has to apply and be approved by the NIH. Note that some research groups who work with the data may include scientists from private companies, who may have the goal of developing commercial

products useful for diagnosis or treatment. There are no plans to share any money or profits with you if the use of your sample(s) results in inventions or discoveries that have commercial value.

Benefits: There is no direct benefit to you for participating in this part of the study. **This research will not diagnose or treat medical problems.** An invitation to participate in genetic research does not imply that you or other family members suffer from a particular disorder or are genetically at risk for a disorder; rather, we are trying to understand how normally occurring variation in individuals' genetic make-up contributes to differences in behavioral outcomes. The hope is that this will allow us to better understand why some people are more likely than others to develop problems associated with use of alcohol and other substances, and/or difficulties with emotional health, and that this information will help people in the future.

How to decline or withdraw from participating: Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled. Please do this by contacting the project coordinator via e-mail at spit4science@vcu.edu or by phone at 804-628-4645. If you choose to withdraw your consent, your sample and associated data will be destroyed.

Questions: If you have any questions:

- **about the study**, contact **Dr. Karen Chartier or the S4S staff at spit4science@vcu.edu or 804-628-4645** (Spit for Science phone line devoted solely to the study; rings through to Project Staff).
- **about your rights as a research subject or general concerns** you may contact:
Office of Research
Virginia Commonwealth University
800 East Leigh Street, Suite 3000
Box 980568
Richmond, VA 23298
(804) 827-2157

Consent to participate. If you select the "Yes..." option then you are indicating that you have read and you understand this consent and any questions you may have had were answered to your satisfaction. ***You freely consent to participate in providing DNA to the Spit for Science Registry and give your permission to have your data and information used as described in this consent document.***

The options below were provided online:

- Yes, I understand this and want to provide a DNA sample to Spit for Science: The VCU Student Survey.
- I want to think about it more before making a decision about participation.
- No, I do not want to participate in the DNA portion of Spit for Science at this time.