

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 take home 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. 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.

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. You will receive \$10 for your time and effort. 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.

The risk to you of participating in this part of the study is the possibility of your identity being linked with your DNA. However, we take many precautions to keep all information we collect from you strictly confidential. 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. Your identity will not be revealed in any publication that may result from this study. Additionally, a data and safety-monitoring plan has also been established.

As another precaution, all of the information collected in this study is protected under a Certificate of Confidentiality issued by the Federal Government. 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 Certificate prevents us from being compelled to reveal your identity or the information you have given us, even under court order, unless you give written permission for us to do so. We will use this Certificate to protect the confidentiality of your data. Additional details about the protections and limitations associated with a Certificate of Confidentiality can be found at <http://grants.nih.gov/grants/policy/coc/>.

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.

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. If profits are made from research using publicly available resources, these would not be distributed back to participants or their family members.

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.

You are free to stop your participation and withdraw your consent at any time without penalty. 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, please feel free to contact:

Dr. Danielle Dick

804-628-4645 (Spit for Science phone line devoted solely to the study; rings through to Project Staff).

If you have general questions 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

PO Box 980568

Richmond, VA 23298

(804) 827-2157

Please call this number if you cannot reach the research team or wish to talk to someone else. Additional information about participation in research studies can be found at <http://www.research.vcu.edu/irb/volunteers.htm>.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

I agree to participate in the DNA collection portion of Spit for Science: The VCU Student Survey.

Name (please PRINT)

Signature

Date

Witness/ Research Assistant

Date