

CADD ASSENT/CONSENT FORM-05/06

Michael Stallings, Ph.D.

Family Study Component

Please read the following material that explains this research study. Signing this form will indicate that you have been informed about the study and that you want to participate. We want you to understand what you are being asked to do and what risks and benefits—if any—are associated with the study. This should help you decide whether or not you want to participate in the study.

You are being asked to take part in a research project conducted by the researcher whose name is listed above at the University of Colorado--Boulder's Institute for Behavioral Genetics, 0447 UCB, Boulder, CO 80309-0447. The researcher can be reached at 303-492-7362.

Project Description:

You, or your sibling, previously participated in this study which is trying to understand the causes of drug, alcohol, and behavior problems in families. One potential cause is heredity. DNA, a chemical in every person's body, contains the genes for each person's heredity. You are being asked to take part again because we are doing follow-ups with all willing former participants, and some siblings who were unable to participate previously, to investigate changes in behavior over time and what those changes can tell us about the causes of those behaviors. The study is voluntary. You do not have to participate.

Procedures:

If you agree to take part in this study, the researchers will again ask the questions they asked before about whether you were an active or quiet person, and about your moods, feelings, drug use, sexual activities, unlawful behavior, and so forth. The interview and questionnaire process can take between 2 to 5 hours to complete but usually lasts about 2 to 3 hours. If, for some reason, the session runs longer than that, you can choose to complete it at a later time. In some cases, we may, if you agree, conduct the session over the telephone.

The researchers may ask other members of your family to participate also and to answer some of these same questions about you.

You may be asked to contribute another DNA sample. This will either be done by having you spit into a collection tube or rinsing your mouth with a provided mouthwash and spitting into a collection tube. This will take about a minute. The researchers will keep some of the DNA that they get from those mouth samples.

We would like to schedule a session for you at the Institute for Behavioral Genetics for about 3 hours at your convenience. If necessary, we may schedule the session in your home or another quiet place such as a school or library.

Researchers will use the information about you (and others) to try to locate genes involved in behavioral choices through their action in the central nervous system by comparing what you said about yourself with the map of genes in your cells and by studying the similarity of relatives' behavior in relation to their genetic similarity. The behaviors studied may include all those we asked you about in the interview and questionnaire described above. We may also use the DNA and to count the frequencies of genetic variations. Careful characterization of the genetic variation in the populations and subpopulations we study helps avoid false or misleading results.

_____ Initials

We may ask you to participate in future studies. Some of our research will be most useful if we can plan future studies to include individuals or relatives who have particular genetic variants at specific genes. To achieve this, we will first identify those individuals or relatives based on their DNA, and then will recontact some participants to ask if they would be willing to participate in future studies. We will also recontact participants who do not have those particular variants to serve as controls; thus being contacted will not in and of itself be informative about any particular trait.

Approximately 1600 Family Study participants will be invited to participate in this research study.

Risks/Discomforts and Benefits:

The risks of physical discomfort or injury are minimal. There is a small chance that you could get distressed or embarrassed about the interviews or DNA spit collection. If that happens the researchers will provide you with information for contacting local counselors or therapists who can discuss those problems with you. The primary potential risk is a break in secrecy; protection from that risk is described below in the **Confidentiality** section.

There are no direct benefits to you for being in this study. If you ask for it, new findings from this research study will be reported to you.

Source of Funding:

This study is being funded by the National Institutes of Health, a federal agency that requires that data be collected in a form that may be analyzed for differences between men and women and races or ethnic groups.

Cost to Participant and Subject Payment:

There is no cost to you for participation in this study. You will be paid \$50 in cash for an in-person interview or by check in the amount of \$30 for completion of a telephone interview and \$20 for completion of the questionnaire. We will also reimburse you for your local travel expenses for an in-person interview by check at the rate of 28 cents per mile.

Injury and Compensation:

If you feel that you may have been harmed while participating in this study, you should inform Dr. Stallings at 303-492-7362 immediately. If you are injured, the University will not be able to pay for your medical care. State law may limit the University's legal responsibility if an injury happens because of this study; claims against the University must be filed within 180 days of the injury.

Study Withdrawal:

You have the right to withdraw your consent or stop participating at any time. You have the right to refuse to answer any question(s) or participate in any procedure for any reason.

_____ Initials

Confidentiality:

To protect your privacy, all of your answers on the materials you previously completed along with these new materials and your DNA data will be held in the strictest confidence. Your name does not appear on any of the interviews or questionnaires. All of the information about you is stored in password-protected computer files with code numbers only, not with your name. Any information which does have your name will be kept locked up and separate from both your DNA and your interview responses. The researchers will safely store your DNA, questionnaire and interview responses indefinitely so they can use it for other studies in the future. Any new study would also be reviewed by an Institutional Review Board. However, you may also ask to have your DNA samples removed from any further studies by notifying the research team in writing.

In addition, a Certificate of Confidentiality has been obtained from the U.S. Department of Health and Human Services (DHHS). This certificate will protect the investigators from being forced to release any research data in which you are identified even under a court order or lawful subpoena. However, you may still voluntarily request that your own data be released. Further, authorized personnel from the funding agency at the National Institute of Health may request information only as needed to evaluate the progress of the research to protect against fraud in federal research programs. The exception to the promise of confidentiality is that if information is revealed concerning abuse or neglect of a child or at-risk adult, or potentially dangerous future behavior involving a serious threat of imminent physical violence against a specified person or persons, we will report this to the proper authorities. Other than the research team, only regulatory agencies such as the Office of Human Research Protections and the University of Colorado Human Research Committee, and NICHD may see your individual data as part of routine audits.

Invitation for Questions:

If you have questions about this study, you should ask the researcher before you sign this consent form. You may also ask questions during or after the session. If you have questions regarding your rights as a participant, any concerns regarding this project or any dissatisfaction with any aspect of this study, you may report them -- confidentially, if you wish -- to the Executive Secretary, Human Research Committee, 26 UCB, Regent Administrative Center 308, University of Colorado at Boulder, Boulder, CO 80309-0026 or by telephone to (303) 492-7401.

Authorization:

I have read this paper about the study or it was read to me. I know the possible risks and benefits. I know that being in this study is voluntary. I choose to be in this study. I know that I can withdraw at any time. I have received, on the date signed, a copy of this document containing 3 pages.

Name of Participant (printed) _____ Age _____

Signature of Participant _____ Date _____
(also, initial all previous pages of the consent form)

<p>For HRC Use Only</p> <p>This consent form is approved for use from _____ to _____.</p> <p>_____ Panel Coordinator, Human Research Committee</p> <p>(Signature)</p>
