

CADD PARENTAL PERMISSION 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 give permission for your child to participate. We want you to understand what your child is 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 your child to participate in the study.

Your child is 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:

Your child, or his/her 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. Your child is 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. Your child does not have to participate.

Procedures:

If your child agrees to take part in this study and you give permission for him/her to do so, 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, your child can choose to complete it at a later time.

The researchers may ask other members of the family to participate also and to answer some of these same questions about him/her.

Your child may be asked to contribute another DNA sample. This will either be done by having him/her spit into a collection tube or rinsing his/her 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 your child 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 your child (and others) to try to locate genes involved in behavioral choices through their action in the central nervous system by comparing what he/she said about him/herself with the map of genes in his/her cells and by studying the similarity of relatives' behavior in relation to their genetic similarity. The behaviors studied may include all those we asked 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 your child 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 your child could get distressed or embarrassed about the interviews or DNA spit collection. If that happens the researchers will provide you and him/her with information for contacting local counselors or therapists who can discuss those problems. 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 for being in this study. If you or your child 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 for participation in this study. Your child will be paid \$50 in cash for an in-person interview. We will also reimburse you for your local travel expenses by check at the rate of 28 cents per mile.

Injury and Compensation:

If you feel that your child may have been harmed while participating in this study, you should inform Dr. Stallings at 303-492-7362 immediately. If he/she is 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 and/or your child have the right to withdraw your consent or stop participating at any time. He/she has the right to refuse to answer any question(s) or participate in any procedure for any reason.

_____ Initials

Confidentiality:

To protect your child's privacy, all of his/her answers on the materials previously completed along with these new materials and his/her DNA data will be held in the strictest confidence. His/her name does not appear on any of the interviews or questionnaires. All of the information about him/her is stored in password-protected computer files with code numbers only, not with your name. Any information which does have his/her name will be kept locked up and separate from both the DNA and the interview and questionnaire responses. The researchers will safely store the 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 or child 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 he/she is identified even under a court order or lawful subpoena. However, he/she may still voluntarily request that his/her 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 or your child have questions about this study, you and he/she should ask the researcher before you sign this consent form. Your child may also ask questions during or after the session. If you or your child have questions regarding your child's rights as a participant, any concerns regarding this project or any dissatisfaction with any aspect of this study, you or your child 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.

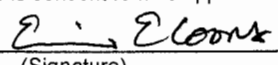
Authorization:

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 allow my child to be in this study. I know that I can withdraw this permission at any time. I have received, on the date signed, a copy of this document containing 3 pages.

Name of Participant (printed) _____ Age _____

Parent (mother)/Guardian Signature _____ Date _____
(also, initial all previous pages of the consent form)

Parent (father)/Guardian Signature: _____ Date _____
(also, initial all previous pages of the consent form)

For HRC Use Only	
This consent form is approved for use from <u>4/20/06</u> to <u>4/19/07</u> .	
	Panel Coordinator, Human Research Committee
(Signature)	