

**CADD CONSENT FORM-02/15/11**  
**Michael Stallings, Ph.D.**

*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 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 other family members, previously participated in a 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 primary CADD subjects and their siblings as well as some siblings and parents 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. If you are on any kind of judicial supervision, your choice to participate in this study will have no effect on how you are treated under that supervision.

**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 some of your siblings 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 on the telephone or 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. If the interview is conducted on the telephone we will ask you to complete a questionnaire online. If you prefer we will mail the questionnaire to you along with a postage paid envelope to return it to us.

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.

Approximately 9,680 participants have been or will be invited to participate in the 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. It is also possible that you may become concerned about your HIV risk. If that happens the researchers will provide you with information for contacting local counselors or therapists or HIV counseling centers for help with 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 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 \$100 in cash for an in-person interview or by check in the amount of \$60 for completion of a telephone interview and \$40 for completion of the questionnaire. We will also reimburse you for your local travel expenses for an in-person interview by check at the current CU-Boulder rate.

**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. The cost for any treatment will be billed to you or your medical or hospital insurance. The University of Colorado at Boulder has no funds set aside for the payment of health care expenses for this study.

### Ending your participation:

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.

In addition to the research to which you are consenting under this study, we are requesting permission to send your genomic (the DNA sample) and phenotypic (your answers to our questions) information, collected at this and previous sessions, to the National Institutes of Health (NIH) in Washington where it will be kept indefinitely. The NIH may give this information to qualified scientists around the world. These scientists will keep the information confidential. The data will have been stripped of personal identifiers (names, addresses, birthdates, and test dates). At NIH the ID code which could provide a link to identifying information is replaced with a NIDA ID. The NIDA agreement with scientists allowed access to the data further prohibits any effort to identify individuals. Any future research would be approved by an ethics committee. which will allow the scientists to do the research without talking to you again since your information will not be identifiable. The use of DNA samples could enable researchers to develop medical tests or treatments that would have commercial value. There are no plans to provide financial compensation to you should this occur.

*Please initial only ONE line below:*

\_\_\_\_\_ I consent to the following: The NIH may store my data (as described in the above paragraph) for future use by scientists around the world for **any kind of genetic research** .

OR

\_\_\_\_\_ I consent to the following: the NIH may store my data (as described in the above paragraph) for future use by scientists around the world only for **genetic studies of substance abuse or related medical problems** .

OR

\_\_\_\_\_ Do not send my information to the NIH.

### 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.

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 Institutional Review Board, 3100 Marine Street, Rm A15, 563 UCB (303) 735-3702.

**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 4 pages.

Name of Participant (printed) \_\_\_\_\_ Age \_\_\_\_\_

Signature of Participant \_\_\_\_\_ Date \_\_\_\_\_  
(also, initial all 4 previous pages of the consent form)