CADD PARENT DNA CONSENT FORM-05/06
John K. Hewitt, Ph.D.
Twin 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 named 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 children 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 collecting DNA from the willing parents of all study participants. The study is voluntary. You do not have to participate.

Procedures:

If you agree to take part in this study, the researchers will ask you to contribute a 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 will either collect this sample at the time we interview your children or mail you a kit for you to return to us by mail.

We will use your DNA for error checking of the samples provided by your children 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.

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 3400 Twin Study participants along with 1400 sets of parents 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 embarrassed by the DNA spit collection. 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.

_____ Initials

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. If the sample collection occurs separately from your children's interviews, you may be paid $20 by check for your participation.

Injury and Compensation:

If you feel that you may have been harmed while participating in this study, you should inform Prof. Hewitt at 303-492-7362 immediately. If you are injured, the University will not 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.

Confidentiality:

To protect your privacy, your DNA data will be held in the strictest confidence. Your name does not appear on your sample. All of the information about you is stored in password-protected computer files with code numbers only. Any information which does have your name will be kept locked up and separate from your DNA. The researchers will safely store your DNA 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.

_____ Initials

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) _____

Signature of Participant _____ Date _____
(also, initial all 3 previous pages of the consent form)

For HRC Use Only

This consent form is approved for use from 4/20/06 to 4/19/07.

E. Eloons Panel Coordinator, Human Research Committee
(Signature)

CADD PARENT DNA CONSENT FORM-05/06
Robin Corley, Ph.D.
CAP Component

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E. E Coons Panel Coordinator, Human Research Committee
(Signature)