DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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July 6, 2006

Stein Sture, Ph.D.
Interim Vice Chancellor for Research and
Interim Dean of the Graduate School
University of Colorado at Boulder
308 Regent Administrative Center, 26 UCB
Boulder, CO 80309-0026

RE: Human Research Subject Protections Under Federalwide Assurance FWA 3492

Research Project:	**Behavioral Genetic Analyses of Executive Functions**
Principal Investigator:	**John K. Hewitt, Ph.D.**
HHS Project Number:	**R01MH63207**
UC IRB Number:	**0600.01**
Research Project:	**Workshop on Methodology of Twin Studies**
Principal Investigator:	**John K. Hewitt, Ph.D.**
HHS Project Number:	**R25MH019918**
Research Project:	**Heritable Early Indicators of Risk for Drug Dependence; Component 4 of Antisocial Drug Dependence: Genetics and Treatment (CADD-4)**
Principal Investigator:	**John K. Hewitt, Ph.D.**
HHS Project Number:	**P60DA11015**
UC IRB Number:	**0897.09**

Dear Dr. Sture:

The Office for Human Research Protections (OHRP) has reviewed the University of Colorado at Boulder's (UCB) May 23, 2006 report submitted in response to OHRP's April 11, 2006 letter regarding the above-referenced research.

After reviewing your report, OHRP notes the following:

(1) In its April 11, 2006 letter, OHRP found that:

(a) Certain subjects were enrolled in the Executive Functions Study and the CADD-4 Study without obtaining the legally effective informed consent of the subject or the subject's legally authorized representative, as required by Department of Health and Human Services (HHS) regulations at 45 CFR 46.116.

(b) UCB was unable to provide documented evidence of parental permission for certain children involved as subjects in the Executive Functions Study and the CADD-4 Study, as required by HHS regulations at 45 CFR 46.408(d).

(c) UCB was unable to provide documented evidence of assent for certain children involved as subjects in the Executive Functions Study and the CADD-4 Study, as required by HHS regulations at 45 CFR 46.408.

OHRP required that UCB provide a report on the implementation of the corrective actions described in the UCB's earlier report dated May 5, 2005. OHRP acknowledges that UCB has (i) provided training to research staff on properly obtaining and documenting informed consent of subjects; (ii) conducted quality assurance reviews; and (iii) developed new standard operating procedures describing how it will review and report incidents of noncompliance to OHRP.

UCB has also indicated that it will provide education to senior leaders of the institution on the importance of protection of human subjects and maintaining the confidentiality of data.

OHRP finds that the corrective actions noted above, as well as those noted in OHRP's April 11, 2006 letter, adequately address the above findings and are appropriate under the UCB FWA.

(2) As part of its April 11, 2006 letter, OHRP raised an additional question regarding exculpatory language in UCB informed consent documents. OHRP acknowledges that UCB has altered its standard language to eliminate any appearance of waiving research subjects' rights, while retaining the factual information that Colorado state law includes a provision requiring injury claims against a public entity to be made within 180 days of discovery of the injury. OHRP finds that UCB has adequately addressed this concern.

As a result of the above determinations, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter these determinations.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Ms. Sheryl Jensen, HRC Executive Secretary, UC
Dr. Margaret Lecompte, Chair, IRB #1, UC
Dr. Thomas Kunstman, Chair, IRB #2, UC
Dr. Sam Shakar, NIH
Ms. Laura Rosenthal, NIH/NIDA
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borror, OHRP
Dr. Irene Stith-Coleman, OHRP
Ms. Patricia El-Hinnawy, OHRP