

## Appendix I: CDC IRB Approval Letter

DATE: 2/13/2007

FROM: IRB-C Administrator  
Human Research Protection Office  
Office of Scientific Regulatory Services  
Office of the Chief Science Officer, OD/CDC

SUBJECT: Site Restricted - IRB Approval of Continuation of Protocol #4169, "National CADDRE Study: Child Development and Autism" (Expedited)

TO: Diana Schendel, PhD [DCS6]  
NCBDDD/DBDDD

CDC's IRB "C" has reviewed and approved your request to continue protocol #4169 for the maximum allowable period of one year and it will expire on 2/18/2008. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), Categories 3, 5 and 7.

**Collaborator Documentation: Please note that current IRB approval documentation is outstanding for John Hopkins School of Public Health and California Health and Human Services Agency. Study activities may not begin/continue with these collaborators/sites until documentation indicating current IRB approval has been received and is on file with the Human Research Protection Office at CDC.**

If other institutions involved in this protocol are being awarded CDC funds through the CDC Procurement and Grants Office (PGO), you are required to send a copy of this IRB approval to the CDC PGO award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided PGO with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

As a reminder, the IRB must review and approve all human subjects research protocols at intervals appropriate to the degree of risk, but not less than once per year. There is no grace period beyond one year from the last IRB approval date. It is ultimately your responsibility to submit your research protocol for continuation review and approval by the IRB. Please keep this approval in your protocol file as proof of IRB approval and as a reminder of the expiration date. To avoid lapses in approval of your research and the possible suspension of subject enrollment and/or termination of the protocol, please submit your continuation request at least six weeks before the protocol's expiration date of 2/18/2008.

Any problems of a serious nature should be brought to the immediate attention of the IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for IRB approval before they are implemented.

If you have any questions, please contact the Human Research Protection Office at (404) 639-4721 or e-mail: [huma@cdc.gov](mailto:huma@cdc.gov).

Jennifer McCleary

cc:  
NCBDDD Human Subjects Review  
Amy Sandul

I have received the documentation and logged into the database. This removes the site restriction for the two collaborators listed below.

Please forward a copy of final approval from John Hopkins as soon as it is available. This final approval will indicate the expiration date of the approval.

Thanks,  
Jennifer