

DATE: 3/16/2009

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

SUBJECT: Extension of IRB Approval for Continuation of Protocol #4169, "Study to Explore Early Development (SEED) (formerly CADDRE)" (Expedited)

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

CDC's IRB "C" has completed the review of the continuation and has approved your request to continue protocol #4169. Approval of #4169 has been extended to the maximum allowable period of one year and it will now expire on 2/18/2010. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), Categories 3, 5 and 7.

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 along with available IRB approvals from all collaborators. 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 along with all completed supporting documentation at least six weeks before the protocol's expiration date of 2/18/2010.

Any problems of a serious nature must 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.

Jennifer McCleary

cc:
NCBDDD Human Subjects Review
Marques Harvey

