# ATTACHMENT N

CDC Institutional Review Board Approval

DATE: 7/22/2008

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 New Protocol #5339, "The Natural History of Spina Bifida in Children Pilot Project" (Expedited)

TO: ANN ALRIKSSON-SCHMIDT [SAX3]
NCBDDD/DHDD

New protocol #5339 has been approved by CDC IRB "C" for the maximum allowable period of one year and it will expire on 7/21/2009. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), categories 4, 5 and 7. The IRB determined that the study poses no greater than minimal risk to subjects and also approved the inclusion of children under 46.404 (research not involving greater than minimal risk to children).

The IRB approved the following waivers:

a. Waiver of alteration of consent for omission of contact information and discussion of risks and benefits in accordance with 45 CFR 46.116(d). This information will be provided to participants by alternate means.

b. Waiver of documentation of informed consent/parental permission
for the telephone survey in accordance with 45 CFR 46.117(c)(2).

**Collaborator Site Restrictions:**

**a. TKCIS: Collaborator must obtain a federal wide assurance (FWA) with the Office of Human Research Protection. Once the FWA # has been obtained, CDC's Human Research Protection Office (HRPO) will initiate the IRB Authorization Agreement for TKCIS to rely on the CDC IRB. Study activities may not begin with this collaborator until the authorization agreement has been approved by TKCIS and CDC and PI has been notified by HRPO that study activities may begin with this collaborator.**

**b. National Opinion Research Center: Study activities may not begin until documentation indicating current IRB approval has been received by CDC's Human Research Protection Office (HRPO) and the PI has been notified by HRPO that this restriction has been lifted and study activities may begin.**

c. **Children's Healthcare of Atlanta at Scottish Rite: Study activities may not begin until documentation indicating current IRB approval has been received by CDC's Human Research Protection Office (HRPO) and the PI has been notified by HRPO that this restriction has been lifted and study activities may begin.**

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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 7/21/2009.

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.

Jennifer McCleary

cc:
NCBDDD Human Subjects Review
Laura Youngblood