Appendix L. 2008 Methodological Study IRB Approval Letter

From: McCleary, Jennifer (CDC/OD/OCSO) on behalf of Human Subjects Review-OD (CDC)
Sent: Tuesday, July 10, 2007 9:58 AM
To: Eaton, Danice (CDC/CCHP/NCCDPHP)
Cc: Redmond-Leonard, Joan A. (CDC/CCHP/NCCDPHP)
Subject: 5177: Removal of Site Restriction - IRB Approval of New Protocol (Expedited)

The Human Research Protection Office has received the requested documentation indicating current IRB approval from ORC Macro. The site restriction for this collaborator is hereby removed and study activities may begin on this study.

Thanks,

Jennifer McCleary
IRB-C Administrator
Human Research Protection Office/OCSO

From: McCleary, Jennifer (CDC/OD/OCSO)
Sent: Friday, June 15, 2007 7:52 AM
To: Eaton, Danice (CDC/CCHP/NCCDPHP)
Cc: Redmond-Leonard, Joan A. (CDC/CCHP/NCCDPHP); Braun, Paula A. (CDC/CCHP/NCBDDD); Sandul, Amy (CDC/CCID/NCHHSTP)
Subject: 5177: IRB Approval of New Protocol (Expedited)

DATE: 6/15/2007

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 New Protocol #5177, "2008 Methodological Study of the Youth Risk Behavior Survey" (Expedited)

TO: Danice Eaton [DHE0]
NCCDPHP/

New protocol #5177 has been approved by CDC IRB "C" for the maximum allowable period of one year and it will expire on 6/14/2008. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), category 7. The Board approved the inclusion of children under 46.404 (research not involving greater than minimal risk to children).

The Board also approved the following in accordance with 45 CFR 46.117(c)(2): waiver of documentation of informed consent for the participation of principals and waiver of documentation of minor assent for the participation of school children.

Collaborator Site Restriction: Study activities may not begin with the following collaborator/site until documentation indicating current IRB approval has been received by CDC and is on file with this office:

ORC Macro

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 6/14/2008.

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.

Jennifer McCleary

cc:
Paula Braun
Joan Redmond-Leonard
Amy Sandul