ATTACHMENT p

CDC Institutional Review Board – Approval Notification

From: Roberson, Lashonda (CDC/OD/OCSO)
Sent: Monday, May 18, 2009 2:43 PM
To: Royalty, Janet (CDC/CCHP/NCCDPHP)
Cc: Redmond Leonard, Joan (CDC/CCHP/NCCDPHP)
Subject: FW: Approval of Continuation of Protocol #1976

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

DATE: May 18, 2009

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

SUBJECT: CDC IRB Approval of Continuation of Protocol #1976.0, "Collection and Analysis of Minimum Data Elements Data Set from the National Breast and Cervical Cancer Early Detection Program (NBCCEDP)" (Expedited)

TO: Janet Royalty
NCCDP/DCPC

CDC's IRB "B" has reviewed and approved the request to continue protocol #1976.0, " Collection and Analysis of Minimum Data Elements Data Set from the National Breast and Cervical Cancer Early Detection Program (NBCCEDP)", for the maximum allowable period of one year. CDC IRB approval will expire on 5/17/2010. The continuation action was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), category 5.

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 5/17/2010.

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 your National Center Human Subjects Contact or the CDC Human Research Protection Office at (404) 639-4721 (or by e-mail at Human Subjects Review - OD on the global CDC global address list or at huma@cdc.gov).

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cc:
Joan Redmond Leonard