NOTICE OF APPROVAL FOR HUMAN RESEARCH

DATE: June 07, 2013
TO: Karen SOKAL-GUTIERREZ, Pub Hlth-JMP
     Ana Alicia LEVIN, Pub Hlth-JMP, Susan L. IVEY, Pub Hlth-JMP, Diana G S, Diana DARAB, Pub Hlth

CPHS PROTOCOL NUMBER: 2011-04-3178
CPHS PROTOCOL TITLE: Risk Factors for Early Childhood Caries in Ecuador
FUNDING SOURCE(S): NONE

A(n) continuing review application was submitted for the above-referenced protocol. The Committee for the Protection of Human Subjects (CPHS) has reviewed and approved the application on an expedited basis, under Category 4,6,7 of the federal regulations.

Effective Date: June 07, 2013
Expiration Date: June 06, 2014

Continuation/Renewal: Applications for continuation review should be submitted no later than 6 weeks prior to the expiration date of the current approval. Note: It is the responsibility of the Principal Investigator to submit for renewed approval in a timely manner. If approval expires, all research activity (including data analysis) must cease until re-approval from CPHS has been received. See Renew (Continue) an Approved Protocol.

Amendments/Modifications: Any change in the design, conduct, or key personnel of this research must be approved by the CPHS prior to implementation. For more information, see Amend/Modify an Approved Protocol.

Three-year approvals: Minimal risk, non-federally funded protocols that are not subject to federal oversight may now be given a three-year approval period. Please see Three Year Approvals for information about which protocols can qualify for three-year approvals.

The addition of federal funding or certain modifications that increase the level of risk may require a continuing review form to be submitted and approved in order for the protocol to continue. If one or more of the following changes occur, a Continuing Review application must be submitted and approved in order for the protocol to continue.
• Changes in study procedures that increase risk;
• Addition of federal funds.

Unanticipated Problems and Adverse Events: If any study subject experiences an unanticipated problem involving risks to subjects or others, and/or a serious adverse event, the CPHS must be informed promptly. For more information on definitions and reporting requirements related to this topic, see Adverse Event and Unanticipated Problem Reporting.

This approval is issued under University of California, Berkeley Federalwide Assurance #00006252.

If you have any questions about this matter, please contact the OPHS staff at 642-7461; fax 643-6272; email ophs@berkeley.edu.
Sincerely,

[Signature]

Robert B. DI MARTINO
Committee for Protection of Human Subjects