



**COMMITTEE FOR PROTECTION OF HUMAN SUBJECTS  
OFFICE FOR THE PROTECTION OF HUMAN SUBJECTS**

University of California, Berkeley  
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Website: <http://cphs.berkeley.edu>  
FWA#00006252

## 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](mailto:ophs@berkeley.edu) .

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Sincerely,

Robert B. DI MARTINO

Committee for Protection of Human Subjects