



Human Research Protection Program  
Office of Research

May 4, 2007

Committee on Human Research  
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3333 California Street, Suite 315  
San Francisco, CA 94118

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UCSF Box 0962

Arthur L. Reingold, MD  
140 Warren Hall  
Berkeley, CA 94720

RE:

**Title of Study:** Assessing the Effectiveness of Tetravalent Meningococcal Conjugate Vaccine among Person Aged 11-21 Years

**Reviewing Campus:** UC Berkeley

**Reviewing Campus Tracking Number:** 2006-10-7

**Reviewing Campus PI:** Arthur L. Reingold, MD

**Reviewing Campus Approval Date:** 12/20/06

**Reviewing Campus Expiration Date:** 12/19/07

**UCSF CHR Tracking Number:** 07030377

**UCSF PI:** Arthur L. Reingold, MD

Dear Dr. Reingold,

This is to acknowledge that the University of California, San Francisco (UCSF), operating under Federalwide Assurance FWA00000068 has received the documentation and Institutional Review Board determination of expedited approval for the above-captioned human subjects research project and intend to rely upon the determination made by the University of California Berkeley IRB operating under Federalwide Assurance FWA00006252. The research, as described in the approved protocol, is now authorized to begin on the UCSF campus.

Any amendments to the protocol, annual renewals, and other required notifications should be submitted to the UC Berkeley IRB for approval, with copies of all submissions to the UCSF HRPP. The authorization to conduct research on the UCSF campus expires on the Reviewing Campus Expiration date, noted above.

The research must be conducted in accordance with all applicable Federal and State Laws, University of California and UCSF Policies, and with the terms of the UC MOU for IRB Review of the Multi-Campus Research.

Please feel free to contact us with any questions.

Sincerely,

Sharon K. Friend, MS  
HRPP Director

cc: UC Berkeley OPHS

**OFFICE FOR THE PROTECTION OF HUMAN SUBJECTS**

University of California, Berkeley  
2150 Shattuck Avenue, Suite 313  
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FWA#00006252

March 21, 2007

ARTHUR REINGOLD (reingold@berkeley.edu)  
Public Health  
140 Warren Hall MC# 7360  
Berkeley, CA 94720

RE: **CPHS Protocol #2006-10-7**

"Assessing the Effectiveness of Tetravalent Meningococcal Conjugate Vaccine among persons aged 11-21 years"  
- Faculty Research - Centers for Disease Control and Prevention (CDC) - Public Health

Dear Professor REINGOLD:

Thank you for submitting an application for approval of amendment to the above-referenced protocol. On 3/20/2007 the following amendments were reviewed and approved on an expedited basis under expedited review category 45 CFR 46.110(b)(2):

- 1) Up to 8 controls per case will be enrolled (4 friend and 4 school-based controls). Neighborhood controls will no longer be used.
- 2) Revision to protocol to include the recruitment process for school controls.
- 3) Change in protocol to provide for the compensation of subjects with a \$10 Target gift card.
- 4) Addition of a separate consent form for controls.
- 5) Changes to existing consent forms to reflect the changes in study procedures and compensation.

The number of this approval remains **2006-10-7**. Please refer to this number in all future correspondence about the project. **The expiration date of the approval also remains 12/19/2007.**

Please note the following:

*The stamped, approved consent materials attached must be used for the consenting of any new subjects.*

*Continuation/Renewal:* Approximately 8 weeks before the expiration of this approval, OPHS will send you a courtesy reminder. Applications for continuation review should be submitted no later than 6 weeks prior to the expiration date of the current approval to allow sufficient time for the renewal process. *Note: It is the responsibility of the Lead Investigator to submit for renewed approval in a timely manner.* In keeping with federal regulations, *if approval expires, all research activity (including data analysis) must cease until re-approval from CPHS has been received.* Before applying, please check current CPHS guidelines, instructions and forms available at <http://cphs.berkeley.edu/content/forms.htm>

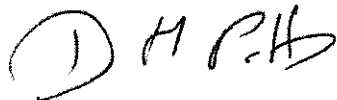
*Amendments/Modifications:* Any change in the design, conduct, or key personnel of this study must be approved by the CPHS **prior** to implementation. (For more information on amendment requests, see "Process for Submission & Review of Applications" and "Application Forms & Informed Consent" on [CPHS website](#)).

*Adverse Events and Unanticipated Events:* If any study subject experiences an adverse and/or unanticipated event involving serious risk, the CPHS must be informed within 48 hours. (For more information on definitions and reporting requirements related to adverse and/or unanticipated events, see "Adverse Events" on [CPHS website](#)).

If you have any questions about the above, please contact the Office for the Protection of Human Subjects staff at (510) 642-7461; Fax (510) 643-6272; or e-mail [ophs@berkeley.edu](mailto:ophs@berkeley.edu).

Thank you for your cooperation and your commitment to the protection of human subjects in research.

Sincerely,

A handwritten signature in black ink, appearing to read "M Potts". The first letter "M" is enclosed in a circle.

Malcolm Potts, M.B., BChir, Ph.D.  
Chair, Committee for the Protection of Human Subjects  
Bixby Professor, School of Public Health

MP: jb

Cc: GRETCHEN ROTHROCK ([grothrock@ceip.us](mailto:grothrock@ceip.us))