

**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS**

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Sacramento, California 95811  
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April 3, 2009

Heidi Bauer, MD, MS, MPH  
CDPH  
850 Marina Bay Parkway, Bldg. P, 2<sup>nd</sup> Floor  
Richmond, CA 94804

Project Title: "Human Papillomavirus Vaccine Impact Monitoring through Surveillance or Cervical Precancerous Lesions"

Project Number: 08-04-51

Dear Dr. Bauer:

The Committee for the Protection of Human Subjects (CPHS), California Health and Human Services Agency, an institutional review board that operates in compliance with the Common Rule under the authority of a Federalwide Assurance (FWA 00000681), reviewed the above-entitled project by expedited review. Please refer to the project title and project number listed above in all future communication with CPHS. The purpose of this letter is to inform you of the CPHS' decisions.

#### Common Rule Approval

The CPHS determined that this project satisfies the requirements of 45 CFR 46.111 and approved the project for the period of one year.

The due date for this project's renewal is **February 26, 2010** if this project is to continue beyond its expiration date of April 2, 2010. Since the CPHS' approval cannot exceed one year pursuant to 45 CFR 46.109(e), CPHS approval will be terminated on the expiration date above unless the CPHS has approved continuation.

Also, if the project is completed or withdrawn it must be submitted to CPHS for approval. Please refer to the CPHS web site ([www.oshpd.ca.gov/boards/cphs](http://www.oshpd.ca.gov/boards/cphs)), "Instructions for Researchers" for submission guidance and deadlines. Although CPHS sends courtesy reminders, it is the Principal Investigator's (PI) responsibility to submit the project renewal on time and to update the CPHS office on changes in the PI and Responsible Official contact information.

Research must be conducted according to the CPHS-approved proposal. CPHS review and approval are required before implementing any changes in your approved study except where necessary to eliminate apparent immediate hazards to human subjects. You are also responsible for the prompt reporting, within 48 hours, to the CPHS of any unanticipated problems or adverse events involving risks to human subjects and others.

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Health Insurance Portability and Accountability Act (HIPAA) Waiver of Authorization

On April 3, 2009, by expedited review, the CPHS approved your request for renewal of a waiver of authorization for protected health information under HIPAA. The CPHS HIPAA waiver of authorization approval is in effect for the term of the project unless there are revisions that affect the HIPAA waiver. The PI must submit to CPHS a request for approval of revisions that affect the HIPAA waiver of authorization.

The protected health information for which the waiver is granted is from laboratories, medical care providers, and KPNC. The variables include name, date of birth, address, phone number, last 4 digits or social security number, ordering provider, CIN diagnosis, CIN treatment, vaccination history, cervical cancer screening history, and immune status, as indicated in the protocol dated February 29, 2008.

Your project qualifies for a waiver of authorization under HIPAA for the following reasons:

- The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals.
  - An adequate plan to protect identifiers from improper use and disclosure has been provided.
  - Adequate written assurance has been provided that the protected health information will not be reused or disclosed to any other person or entity.
  - An adequate plan has been provided to destroy the data at the completion of the study.
- The research could not practicably be conducted without a waiver of authorization.
- The research could not practicably be conducted without access to and use of the protected health information.

If you have any questions, please contact our office at 916-326-3660 or [cphs-mail@oshpd.ca.gov](mailto:cphs-mail@oshpd.ca.gov).

Sincerely,



Joan M. Mock  
Assistant Administrator