



Human Research Protection Program
Office of Research

July 2, 2007

Committee on Human Research
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www.research.ucsf.edu/chr/index.asp

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Mailing Address:
3333 California Street, Suite 315
San Francisco, CA 94118

Campus Mailing Address:
UCSF Box 0962

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

RE:

Title of Study: The BV Study: Relationships of Lactobacillus and Phages in Bacterial Vaginosis among Women in Mysore, India
Reviewing Campus: UC Berkeley
Reviewing Campus Tracking Number: 2006-8-11
Reviewing Campus PI: Purnima Madhivanan
Reviewing Campus Approval Date: 12/14/06
Reviewing Campus Expiration Date: 8/31/07
UCSF CHR Tracking Number: 07030864
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 full committee 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
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FWA#00006252

December 19, 2006

PUJNIMA MADHIVANAN (mpurnima@berkeley.edu)
Public Health/Epidemiology
140 Warren Hall, MC# 7360
University of California, Berkeley

RE: Approval of CPHS Protocol #2006-8-11
"The BV Study: Relationships of Lactobacillus and Phages in Bacterial Vaginosis among Women in Mysore, India" - Post-doctoral Research - National Institutes of Health - Public Health/Epidemiology

Dear Dr. Madhivanan:

Thank you for submitting responsive materials relative to the above-referenced study. The Committee has reviewed these responses to the request for specific, minor revisions detailed in our letter of September 5, 2006, and has found them to be in order. We have granted final approval, for one year or less, effective December 14, 2006. **This approval will expire on August 31, 2007.**

Please also note the following:

The number of this approval is **2006-8-11**. Please refer to this number in all future correspondence.

The Committee found that this research presents *greater than minimal risk* of harm to the subjects. Therefore, the research must continue to be reviewed by the full committee until data collection has been completed or the study is amended such that the risk of harm to the subject is determined to be minimal.

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 research must be approved by the CPHS *prior* to implementation. (For more information, 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 email ophs@berkeley.edu.

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

Sincerely,



Martin S. Banks, Ph.D
Vice Chair, Committee for Protection of Human Subjects

MSB:mcs

Cc: Professor Arthur Reingold (reingold@berkeley.edu)
Diane Hinkly, Administrative Contact (dmhinkly@berkeley.edu)
Sponsored Projects Office (spo_acuc_ophs@lists.berkeley.edu)
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