

**CHR APPROVAL LETTER**

**TO:** Julius Schachter, Ph.D.  
Box 0842, SFGH

Chandler R. Dawson, M.D.  
Box 0412,

**RE:** Azithromycin in Control of Trachoma II

The Committee on Human Research (CHR) has reviewed and approved this application to involve humans as research subjects. This included a review of all documents attached to the original copy of this letter.

Specifically, the review included but was not limited to the following documents:

**Translation Consent Form, Dated 6/8/06**  
**English Consent Form, Dated 6/8/06**

The CHR is the Institutional Review Board (IRB) for UCSF and its affiliates. UCSF holds Office of Human Research Protections Federalwide Assurance number FWA00000068. See the CHR website for a list of other applicable FWA's.

**COMMENT:** First, the full committee determined that the research, which is now complete for all participants and only genetic sequencing of samples and data analysis are ongoing, poses no greater than minimal risk and is eligible for expedited review under category #9. For future renewals, please follow the instructions for studies initially reviewed using Expedited Review. It is not necessary to redo the CHR application on the expedited form. Second, please note that research involving minors may only be approved by the CHR if the research satisfies specific conditions in federal regulations (Subpart D of 45 CFR 46 and 21 CFR 50). For the record, the members agreed that enrolling minors in this study is acceptable under the provision of federal regulations (45 CFR 46.404, 21 CFR 50.51). The research involves minimal risk. The permission of one parent will be obtained.

**APPROVAL NUMBER:** H1079-17254-09. This number is a UCSF CHR number and should be used on all correspondence, consent forms and patient charts as appropriate.

**APPROVAL DATE:** March 4, 2008

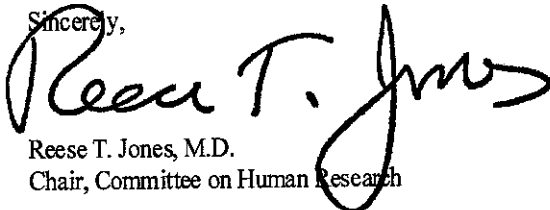
**EXPIRATION DATE:** March 28, 2009

**Full Committee Review**

**GENERAL CONDITIONS OF APPROVAL:** Please refer to [www.research.ucsf.edu/chr/Apply/chrApprovalCond.asp](http://www.research.ucsf.edu/chr/Apply/chrApprovalCond.asp) for a description of the general conditions of CHR approval. In particular, the study must be renewed by the expiration date if work is to continue. Also, prior CHR approval is required before implementing any changes in the consent documents or any changes in the protocol unless those changes are required urgently for the safety of the subjects.

**HIPAA "Privacy Rule" (45CFR164):** This study does not involve access to, or creation or disclosure of Protected Health Information (PHI).

Sincerely,



Reese T. Jones, M.D.  
Chair, Committee on Human Research

cc: Erich Schneider, Box 0842