



JOHNS HOPKINS  
M E D I C I N E

SCHOOL OF MEDICINE

Website: <http://irb.jhmi.edu>

**Office of Human Subjects Research  
Institutional Review Boards**

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TO : Emily Gower, PhD  
Assistant Professor, Ophthalmology  
Wilmer 121  
The Johns Hopkins Hospital

FROM: Laura Rocco, R.N., MS  
Chairman - JHM-IRB X

DATE: 10/19/2007

RE : **Application Number: NA\_00001938, entitled, Rates and Risk Factors for Post-Cataract Surgery Endophthalmitis (with Ashley Behrens, Peter Campochiaro, Peter McDonnell, Oliver Schein, James Tielsch, Lisa Keay)**

I am pleased to inform you that the **JHM-IRB X** approved the continuing review application for the above-referenced research on **10/09/2007**. Approval of the research is for the period of **10/09/2007 to 10/8/2008**. As principal investigator of the research, you are responsible for fulfilling the following requirements of approval:

- 1) The co-investigators listed on the application should be kept informed of the status of the research.
- 2) Changes to the research must be submitted on a "**Changes in Research Application**" to the JHM IRB for review and approval prior to the activation of the changes, with the following exception: changes made to eliminate apparent immediate hazards to the research participant may be instituted immediately and the JHM IRB should be informed of such changes promptly. The application number assigned to the research should be cited in all correspondence.
- 3) Reports of unanticipated problems involving risks to participants or others must be submitted to the JHM IRB in accord with the JHM IRB Guidance: Report of Unanticipated Problems Involving Risks to Participants or others, using the Problem/Event Report Form (on the JHM IRB Website).
- 4) Federal regulations require review of approved research not less than once per year. **Therefore, a continuing review application must be submitted to the JHM IRB office six weeks prior to the expiration date of 10/8/2008. This will allow sufficient time for review of the application to be completed prior to the expiration date.** Failure to submit a continuing review application prior to the expiration date will result in termination of the research, at which point new participants may not be enrolled and currently enrolled participants must discontinue participation in the study.

LR:kjk

CC: Patricia Hawse

**JHM-IRB X**

**CONTINUING REVIEW  
APPROVAL NOTICE  
EXPEDITED REVIEW  
with Waiver of Consent**