



Office for Human Research Protections
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May 23, 2006

Roberto Peccei, Ph.D.
Vice Chancellor - Research
University of California, Los Angeles
2147 Murphy Hall, Box 951405
Los Angeles, CA 90095-1405

**RE: Human Research Subject Protections Under Multiple Project Assurance (MPA)-1127
and Federalwide Assurance FWA- 4642**

**Research Project: Protocol TSVS-701-25G: A Prospective, Non-Randomized,
Multicenter Clinical Evaluation of the 25-Gauge Millennium TM Transconjunctival
Sutureless Vitrectomy System (TSVS) with Entry Site Alignment System (ESAS)**

Principal Investigator: Steven Schwartz, M.D.

UCLA IRB #: 01-11-057-01

Research Project: 25-Gauge Vitrectomy System Registry

Principal Investigator: Anurag Gupta, M.D.

UCLA IRB #: 04-07-004

**Research Project: Clinical Characterization, Genetic Testing, and Visual Function in
Patients with Stargardt's Disease**

Principal Investigator: Steven Nusinowitz, Ph.D.

UCLA IRB #: 04-10-010

Research Project: Genetic Studies in Inherited Ocular Disorders

Principal Investigator: Anthony Aldave, M.D.

UCLA IRB #: 94-07-243-23

**Research Project: Research on intra-ocular pressure of patients receiving Bausch
and Lomb 25-Gauge Trocar System**

**Principal Investigator: Steven Schwartz, M.D., Anu Gupta, M.D., and Christine
Gonzalez, M.D.**

Dear Dr. Peccei:

The Office for Human Research Protections (OHRP) has reviewed the University of California, Los Angeles's (UCLA) April 17, 2006 report responding to determinations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46) involving the above-referenced research.

Based upon its review, OHRP finds that your responses and corrective actions adequately address OHRP's findings, questions and concerns and are appropriate under the UCLA FWA. As a result, OHRP anticipates no further involvement in this matter.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Kristina C. Borrer, Ph.D.
Director
Division of Compliance Oversight

cc: Ms. Judith L. Brookshire, Director, OPRS, UCLA
Dr. Lawrence E. Wolinsky, IRB Chair, General Biomedical IRB #1, UCLA
Dr. Robert A. Figlin, IRB Chair, Cancer/Infec Dis IRB #2, UCLA
Dr. Nancy Levine, IRB Chair, North General Social-Behav IRB#3, UCLA
Dr. Bruce Kagan, IRB Chair, Neuroscience IRB #4, UCLA
Dr. Alison Moore, IRB Chair, South General IRB #5, UCLA
Dr. Steven Schwartz, UCLA
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Ms. Shirley Hicks, OHRP
Dr. Irene Stith-Coleman, OHRP
Ms. Janet Fant, OHRP
Ms. Patricia El-Hinnawy, OHRP