LETTER OF COMPLIANCE

To Whom It May Concern:

HHS Regulations
Massachusetts Eye and Ear Infirmary (MEEI) holds a Federalwide Assurance (FWA00006221) and Schepens Eye Research Institute (SERI) holds a Federalwide Assurance (FWA00008093) from the Office of Human Research Protections. Under these assurances, Massachusetts Eye and Ear (MEE) complies with 45 CFR 46.

FDA Regulations
MEE also complies with the regulations found under 21 CFR 50, 21 CFR 56, 21 CFR 312, and 21 CFR 812.

Institutional Review Board
The Institutional Review Board (IRB) for MEE is known as the Human Studies Committee (HSC). The HSC is composed in accordance with and operates in compliance with FDA and HHS regulations. The HSC is registered with HHS as IRB00000459. The Chairman of the Human Studies Committee is Steven Rauch, M.D.

Belmont Report
MEE adheres to the ethical principles and guidelines for the protection of human research subjects set forth in The Belmont Report.

ICH/GCP Compliance
MEE complies with ICH Guidelines on Good Clinical Practice where they are consistent with FDA and HHS regulations.

Policy on Electronic Signatures
The IRBNet System is fully compliant with the technology requirements for Electronic Records per 21 CFR 11 (Section 11.10 - Controls for Closed Systems) and the technology requirements for Electronic Signatures per 21 CFR 11 (Subpart C - Electronic Signatures). Correspondence to the investigator related to the acknowledgment or approval of an action is generated by Human Research Protections Program staff utilizing IRBNet in accordance with institutional policy and procedures and relevant federal and state requirements.

If you have any questions please call 617-573-3446 or email HSC@meei.harvard.edu.