[redacted] for treatment of Myopia was approved on January 14, 1998 for the [redacted] according to a letter to [redacted] from the FDA dated the same **EXHIBIT #10.**

The clinical investigator then submitted this procedure to the Institutional Review Board, [redacted], for review. It was approved on July 17, 1998, **EXHIBIT #24**, and should be used on all applicable cases after that date.

[redacted] had Bilateral Simultaneous [redacted] on 8/13/98 according to the [redacted] intra-operative form, **EXHIBIT# 25.**

The patient information and consent form was also signed on that same date **EXHIBIT #26.** However, the required Simultaneous Bilateral [redacted] consent form **EXHIBIT #24** was not in the patient file and could not be produced upon request.

[redacted] indicated this was a mistake and they would have to be more careful in the future. The person who is responsible was new and not aware of the IRB approved consent form to be used.

6. IDE [redacted] had [redacted] Enhancements performed which is a condition not indicated in the [redacted] Additionally, the procedures were performed with a laser that is not indicated in the study and the surgery was performed at a location that is not identified in the protocol.

[redacted] was initially diagnosed as a moderately high myope who wished refractive surgery. The patient was enrolled into the research study via consent form and signature **EXHIBIT #27** and received left myopic [redacted] eye surgery on 10/9/97 **EXHIBITS 28 & 29.** He received a moderate overcorrection which resulted in hyperopia **EXHIBIT #29.** Subsequent follow-up visits on 10/30/97, 6/10,29/98, **EXHIBITS 30,31 & 32 respectively,** resulted in [redacted] to deciding a left eye hyperopic [redacted] enhancement was necessary. The patient received left eye hyperopic [redacted] enhancement on 8/19/98 at the [redacted] **EXHIBITS 33 & 34.** There was no evidence of a patient information and consent form in the file for this hyperopic enhancement.