

[REDACTED]
[REDACTED]
10/6,7,8,13,14,15,20
22,23,26,27,30-
11/2/98 RALS

[REDACTED] was diagnosed as a high myope and considered a candidate for [REDACTED] eye surgery on 7/26/97, **EXHIBIT #35**. The patient was enrolled into research study via consent form and signature on 10/7/97, **EXHIBIT #36**.

Bilateral myopic [REDACTED] surgery was performed OS (left eye) on 10/7/98, **EXHIBIT #37** and OD (right eye) on 10/9/98, **EXHIBITS 38 & 39**. **EXHIBITS 40,41,42 & 43** chronicle follow-up visits and circumstances which led to the decision [REDACTED] made to perform hyperopic enhancement on [REDACTED]. On 8/19/98 [REDACTED] had hyperopic [REDACTED] enhancement OD at the [REDACTED] as documented by **EXHIBIT #44**. There was no evidence of a patient information and consent form in the file for this hyperopic enhancement.

[REDACTED] was diagnosed as a high myope and considered a candidate for [REDACTED] eye surgery on 12/1/97, **EXHIBIT #45**. The patient was enrolled into the research study via consent form and signature **EXHIBIT #46**. Bilateral myopic [REDACTED] surgery was performed OS(left eye) on 1/29/98, **EXHIBIT #47 & 48** and OD (right eye) on 2/19/98, **EXHIBIT #49,50 & 51**.

Right hyperopic [REDACTED] enhancement was initially considered on April 9, 1998, **EXHIBIT #52**, and finally performed on July 1,1998, **EXHIBIT #53 & 54**, at the [REDACTED]

The following two patients are not IDE patients [REDACTED], they are included in this report to document Hyperopi [REDACTED] enhancements being performed with a [REDACTED] at the [REDACTED]

[REDACTED] had [REDACTED] eye surgery [REDACTED] and is not enrolled in the research study ([REDACTED]). This patient had bilateral Myopic [REDACTED] surgery OS(left eye) on 10/3/96 by [REDACTED] on 10/17/96 by [REDACTED], **EXHIBIT #55**.

Due to an overcorrection in his right eye and resulting hyperopia a decision was made to perform hyperopic [REDACTED] enhancement to reverse the overcorrection **EXHIBIT #56**. Right hyperopic [REDACTED] enhancement was performed on [REDACTED] on 3/25/98 at the [REDACTED] **EXHIBITS 57 & 58**.

EXHIBIT #59 is an example of the type of consent form that was used for this procedure.