[redacted]
4/19,20,23-30, 5/1-4,7,10/2001 [redacted]

[redacted] Institutional Review Board sent [redacted] a notice dated August 1, 2000, **EXHIBIT #3,** to inform him that the revised protocol dated 7/8/98 in their possession indicated the low myopia population was limited to 400 subjects.

[redacted] reported in a biannual report that was sent to SAIRB the number of myopes had exceeded 400 patients however, he failed to mention that the patient population had been increased by the FDA in Jan. 1999. [redacted] drafted a letter to [redacted] **EXHIBIT #4** dated 8/16/2000 explaining the increase in patient population. SAIRB reviewed the information from [redacted] and responded by letter **EXHIBIT #5** dated August 30, 2000 reapproving [redacted] study for another year.

2. **The firm is not complying with the Investigator Agreement which was signed and dated by the Clinical Investigator at the beginning of the Clinical Study.**

EXHIBIT #6 is an Investor Agreement which was signed by [redacted] Sponsor/Clinical Investigator and [redacted] o-Investigator. The agreement indicates, among other things, the clinical investigators agree to promptly report to the IRB all changes in the research activity. The clinical investigators failed to report the increase in the number of study patients, granted by the FDA, to the IRB in a prompt manner.

3. **There was a lapse of IRB approval for the protocol: [redacted] from 8/3/2000 until 8/29/2000 according to IRB lapse notices and the IRB annual re-approval letter.**

EXHIBIT #7 is a reapproval letter from [redacted] dated 8/4/99 for [redacted] study with an expiration date of 8/3/00. [redacted] wrote [redacted] on August 1, 2000, **EXHIBIT #3** indicating they had not received an update in the form of a report from him concerning the study. The letter also stated the IRB approval will lapse on 8/3/00. [redacted] wrote [redacted] for a second time on 8/7/2000 **EXHIBIT #8** indicating they still had not received any updates concerning the study. The letter also stated [redacted] should cease enrollment on low myopia surgeries and if he chose to amend the protocol to request permission to do more low myopia surgeries he could not begin scheduling the surgeries until the amendment was approved by the IRB. The laser refractive study log **EXHIBIT #2 pgs.12&13** show [redacted] continued performing myopia surgeries throughout the month of August 2000.