

Page 5 - Herbert J. Nevyas, M.D.

10. Your description of study procedures, examination conditions and techniques is not adequate. Please provide a detailed description of each procedure, test and instrument to be used in the study. Standard references may be used for generally accepted tests and instruments, but distances, luminances, and other settings should be provided.
11. On page 134 of your submission you have presented a sample of your Intraoperative Report Form. Operative reports should be completed for all treated subjects, and for those subjects on whom a procedure was attempted but not completed. In addition, the report should include the information on attempted spherical correction, attempted cylindrical correction, number of laser pulses, time for entire procedure, whether procedure was interrupted, drug treatment before, during and after the procedure, and which eye was treated first (and second). Report forms should be in a forced-choice format. Please revise your intraoperative report form or present justification for not conforming with the above recommendations.
12. Please provide a copy of your patient questionnaire.
13. You have indicated that cylinder will be evaluated based on desired versus achieved correction. However, since your study design involves a high degree of astigmatism (up to -7 D), please provide a plan to stratify your results also by astigmatic presentations. Also, for the astigmatic corrections, please report the proportion of eyes that achieve minimal residual astigmatism.
14. In your Informed Consent Document, page 197, please correct or justify the following:
- please provide a statement in one of the initial paragraphs that the study involves research;
 - please provide a statement of the expected duration of the subject's participation;
 - please delete the last sentence in the second paragraph on page 198, which begins, "However, this laser was developed by Dr. Nevyas...."; and,
 - please correct the typographical errors on page 199 which mention Drs. Wong & Thorne.
15. All co-managing practitioners are considered investigators and must sign the investigator agreement prior to their participation. Please certify that all investigators (and co-managers) who will participate in the investigation have signed the Investigator Agreement.