NEV-01-002 (Myopia/Myopic Astigmatism) states that UCVA at near will be performed at Month 3 and the Final Exam. However, the Study Flow Chart in Appendix A indicates that UCVA at near should only be performed at the screening visit. As another example, Section 8.4 of Protocol NEV-97-003 (Hyperopia/Hyperopic Astigmatism) states that UCVA at near will be performed at Month 3 and the Final Exam. However, the Study Flow Chart in Appendix A indicates that UCVA at near should be performed at the screening visit and at Month 3. Please resolve all discrepancies between the text in Section 8.4, the Study Flow Chart, and the footnotes under Notes for the Examination Schedule.

16. You have listed late onset of haze beyond 6 months with loss of 2 lines (10 letters) or more BSCVA as one adverse event, and haze beyond 6 months with loss of $\geq$ 2 lines of BSCVA as another adverse event. Please delete the first version of this haze adverse event from your protocol.

17. You have listed a decrease in BSCVA of more than 10 letters not due to irregular astigmatism as shown by hard contact lens refraction at 6 months or later as a possible adverse event. You have also listed a decrease in BSCVA of $\geq$ 2 lines at 3 months or later as another possible adverse event. Please delete the first version of this decreased BSCVA adverse event from your protocol.

18. Please add a statement to your consent form indicating that there are lasers approved for LASIK for the treatment of myopia with and without astigmatism and hyperopia with and without astigmatism.

19. As part of the discussion of alternatives in your consent form, please discuss intra-corneal rings for the treatment of myopia and thermal keratoplasty for the treatment of hyperopia.

20. The Voluntary Participation section of the consent form states that the study doctor can stop the subject's participation at any time if the subject fails to follow directions for participating in the study, or if it is discovered that the subject does not meet the study requirements. Since this is a device investigation, non-compliance with the study procedures is not an acceptable reason for the subject's discontinuation. In addition, if it is discovered after surgery that a subject did not meet the study requirements, a protocol violation should be noted, but the subject should not be discontinued from the study. Please revise the consent form to clarify these points.

21. The Conclusion section of the consent form states, "There is always a possibility of one or more late complications that were not known or anticipated at the time of this writing (1997)." It also states, "LASIK is investigational surgery and as such, it has not yet been completely and exhaustively studied by the FDA and medical researchers in this country." Please update the consent form as necessary in keeping with current knowledge including the additions previously mentioned. Please revise the second statement to improve its accuracy: LASIK is no longer investigational, it has never