

7. Your protocol states that subjects must have a best spectacle corrected visual acuity (BSCVA) of at least 20/40 in each eye in order to be enrolled in the study. Please be advised that while we find this criteria acceptable for subjects with high myopia (≥ 7 D MRSE), in order for subjects with low myopia (< 7 D MRSE) to be enrolled, we recommend a BSCVA of at least 20/25 in each eye. Please revise your protocol accordingly, or justify not doing so.
8. Please add an inclusion criterion for uncorrected visual acuity (UCVA), e.g., UCVA of worse than 20/40.
9. Protocol NEV-01-002 (Myopia/Myopic Astigmatism) states that subjects must have a stable manifest refraction defined as ≤ 0.5 D change in sphere or cylinder during the year prior to the screening examination for inclusion in the study. Please revise your protocol to indicate that this inclusion criterion applies to subjects with high myopia (≥ 7 D MRSE). Please add that subjects with low myopia (MRSE < 7 D) must have a stable correction (± 0.5 D), as determined by MRSE, for a minimum of 12 months prior to surgery.
10. Similarly, Protocol NEV-97-003 (Hyperopia/Hyperopic Astigmatism) states that subjects must have a stable manifest refraction defined as ≤ 0.5 D change in sphere or cylinder during the year prior to the screening examination for inclusion in the study. Please revise your protocol to indicate that subjects must have a stable correction (± 0.5 D), as determined by MRSE, for a minimum of 12 months prior to surgery.
11. Section 7.2 of your protocol states that subjects wearing hard contact lenses must have 2 refractions and central K readings taken at least 1 week apart that are within 0.5 D for both sphere and cylinder before undergoing LASIK. Please revise this inclusion criterion so that it applies not just to hard contact lens wearers, but all contact lens wearers, and so that it is consistent with the revised inclusion criterion regarding stability referred to above.
12. Your protocol states that subjects who have pupils (measured in dim illumination) that are too large compared to the intended optic zone should be excluded from the study. Please revise your protocol to indicate that subjects with mesopic pupil measurements \geq the planned optic zone should be excluded from the study.
13. Please add axial length measurement to the baseline eye examination.
14. The postop Day 1 (1 to 3 days postop) and Week 1 (5 to 12 days postop) visit windows you have proposed are too long. We recommend the following visit windows - Day 1 (24-36 hours) and Week 1 (5-9 days). Please revise Appendix B accordingly, or justify not doing so.
15. Section 8.4, "Follow-Up Visits", is inconsistent with Appendix A: Study Flow Chart and the Notes for the Examination Schedule. For example, Section 8.4 of Protocol