AMBLYOPIA IN ASTIGMATIC CHILDREN
Development and Treatment

NIH/NEI U10 EY13153

MANUAL OF PROCEDURES

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1. BACKGROUND AND RATIONALE

Evidence from the scientific literature indicates that uncorrected astigmatism during childhood is associated with three types of amblyopia: (1) a difference in best-corrected acuity and contrast sensitivity for orthogonal gratings (meridional amblyopia or MA),\textsuperscript{10,21-23,29,51,52} (2) a difference in best-corrected acuity for orthogonally-oriented vernier acuity stimuli (also termed MA),\textsuperscript{27,51} and (3) a deficit in best-corrected recognition (letter) acuity.\textsuperscript{4,7,17,41,64} These data suggest the presence of a sensitive period for the development of astigmatism-related amblyopia. However, as summarized below, only limited information is available concerning factors that influence the development of astigmatism-related amblyopia, or concerning the sensitive period for its development and effective treatment. This lack of data is undoubtedly related to the low prevalence of high astigmatism among typical urban populations.\textsuperscript{11,30,40,73}

Defining the Sensitive Period for the Development of Astigmatism-Related Amblyopia

Bornstein\textsuperscript{8} provided a framework for research and theory regarding sensitive periods. This framework is useful in summarizing existing knowledge, and in guiding further research. He described four sets of characteristics for defining a sensitive period: (1) temporal and intensive contours, (2) mechanisms involved in sensitive-period change, (3) consequences of the sensitive period, and (4) evolutionary and ontogenetic time scales. Little information regarding these characteristics exists in the literature regarding the sensitive period for astigmatism-related amblyopia.

A. Temporal and Intensive Contours. At what point during development does the sensitive period begin, and end? How much astigmatism must be present for astigmatism-related amblyopia to develop?

Several studies have shown an association between uncorrected astigmatism in infancy or early childhood and the development of MA, as measured with grating or vernier stimuli. Gwiazda et al.\textsuperscript{27,29} reported that six- to eight-year-old children without astigmatism can show MA that is predictable from astigmatism they had during infancy. Atkinson et al.\textsuperscript{3,4} reported that over 50% of children who had >1 diopter (D) of astigmatism after age two years had MA at age four years. Mohindra et al.\textsuperscript{53} reported approximately 0.5 octave of MA in a child 34 months of age with 1.5 D of oblique astigmatism. These studies indicate that the sensitive period begins quite early in development.
Another aspect of defining a sensitive period is to determine the oldest age at which treatment can prevent or reverse the development of amblyopia, i.e., defining the “end” of the sensitive period. The only prospective study addressing this question is by Mohindra et al.,\textsuperscript{53} who documented the presence of MA in a 34-month-old child with 1.5 D of oblique astigmatism, and then found that MA was no longer present after three months of spectacle correction. Indirect evidence suggesting that the sensitive period for development of MA extends at least to age six or seven years comes from two studies of adult astigmats. Mitchell et al.\textsuperscript{51} found no evidence of MA in one adult who received glasses prior to age six, while Cobb and MacDonald\textsuperscript{10} found no evidence of MA in three of six astigmatic adults who received glasses prior to age seven. In contrast, MA was present in six astigmatic adults in the Cobb and MacDonald\textsuperscript{10} study who received glasses after age seven, and in 27 of the 37 adults in the Mitchell et al.\textsuperscript{51} study who received glasses after age six. Unfortunately, these two studies of adults provide no data on age at onset of astigmatism, or whether the glasses that the individuals received during childhood were prescribed in order to correct astigmatism. Thus, it is impossible to know whether the ten adults in the Mitchell et al.\textsuperscript{51} study who got glasses after age six but did not show MA: (a) benefitted from a sensitive period that extends past age six; or (b) failed to develop astigmatism until they were too old to develop MA, i.e. after the end of the sensitive period.

B. \textit{Mechanisms Involved in Sensitive-Period Change}. What are the consequences of various aspects of astigmatism, such as the amount of astigmatism, type of astigmatism (e.g., simple myopic, compound myopic, etc), and the orientation (axis) of astigmatism on visual outcome?

\textbf{Amount of Astigmatism}. The relation between amount of astigmatism and magnitude of astigmatism-related amblyopia is not well understood. Data from 100 Tohono O’Odham optometry patients indicated that prevalence of amblyopia increased with increasing amounts of astigmatism.\textsuperscript{17} Similarly, Mitchell et al.\textsuperscript{51} found a significant tendency for MA to increase with increasing astigmatism. However, Mitchell et al. found considerable variability among subjects: among the 15 subjects with astigmatism >2.75 D, MA ranged from 0.0 to nearly 1.0 octave. Similarly, Cobb and MacDonald\textsuperscript{10} found MA that ranged from 0.1 to 0.4 octave among 12 eyes with >3.00 of astigmatism. Thus, factors other than amount of astigmatism must influence presence and amount of astigmatism-related amblyopia.
Developmental Course and Axis of Astigmatism. Sjöstrand and Abrahamsson conducted a four-year follow-up study of a sample of 310 infants who had $1 \text{ D}$ of astigmatism at age one year. Those with astigmatism that increased between ages one and four years and those with oblique astigmatism were at highest risk for amblyopia, defined as a best-corrected acuity difference between eyes of 0.1 log unit or more on two separate occasions, with an improvement of at least one line following occlusion treatment of the amblyopic eye. Thus, this study suggests that the developmental course of astigmatism (changes with age) and axis of astigmatism influence the development of astigmatism-related amblyopia.

Type of Astigmatism. Mitchell et al., in their study of 38 astigmatic adults, found that acuity was best for gratings oriented parallel to the hyperopic focal line that was located nearest to the retina, but found no evidence that type of astigmatism, e.g. mixed or compound hyperopic, influenced presence or amount of MA. In contrast, results presented by Gwiazda et al. for six non-astigmatic six-year-old children who had 1.75 to 3.50 D of astigmatism as infants, indicated that four who had had astigmatism with one myopic focus showed significant MA, whereas two who had had compound hyperopic astigmatism did not. Clearly, additional data are needed to explore the relation between location of astigmatic foci and the development of amblyopia.

C. Consequences of the Sensitive Period. What aspects of function are influenced by presence of astigmatism during the sensitive period? Evidence exists indicating that the consequences of astigmatism during the sensitive period include differences in grating acuity, vernier acuity, and contrast sensitivity for orthogonally-oriented stimuli, and deficits in recognition acuity.

Grating Acuity. MA, a non-optical difference in visual acuity for orthogonally-oriented gratings, has been shown to be present in astigmatic adults and in non-astigmatic children who had astigmatism during infancy. In the earliest studies of MA, Mitchell, Freeman, and colleagues, showed that the orientation of gratings that is seen best by an astigmatic individual can be predicted from the axis of the astigmatism and from the location of the two principal foci of the astigmatic eye. The magnitude of MA is usually between 0.3 and 0.5 octave, but differences up to 1.0 octave have been reported.
Vernier Acuity. Most studies of MA have measured visual acuity for orthogonally-oriented grating stimuli. Two studies, however, compared vernier acuity for vertically-oriented “broken line” stimuli to vernier acuity for horizontally-oriented “broken line” stimuli\(^27,51\) and found MA that was greater than that previously reported for grating stimuli. For example, four of seven non-astigmatic children who had $1.0$ D of astigmatism in infancy showed MA for vernier stimuli that ranged from 1.5 to 2.5 octaves.\(^27\) In contrast, the maximum difference previously reported for orthogonally-oriented grating stimuli is about 1.0 octave.\(^10,22,29,51\) Among non-astigmatic children with MA for vernier stimuli, amount of astigmatism at age 6 to 12 months was roughly correlated with amount of MA at school age.\(^27\)

Contrast Sensitivity. In contrast to measurements of grating acuity and vernier acuity, which provide data on the ability to detect high spatial frequency stimuli, measurements of contrast sensitivity provide information on the detectability of stimuli across a broad range of spatial frequencies. Studies of contrast sensitivity in astigmatic adults tested with optical correction have reported a difference in sensitivity to orthogonally-oriented gratings (MA) at spatial frequencies from 1 to $>20$ cycles/deg.\(^{21,23,52}\) In addition, Daugman reported data from a non-astigmatic adult indicating a sensitivity to horizontal gratings that was about three times greater than that to vertical gratings, and suggested that this resulted from astigmatism that was present prior to age five years.\(^15\)

Recognition Acuity. Individuals who have MA would be expected to have deficits in recognition acuity, since recognition acuity is typically measured with letters or symbols composed of lines of differing orientations. This expectation was confirmed by Atkinson et al.,\(^4\) who used the Cambridge Crowding Cards to test recognition acuity in 18 four-year-old children with MA, and found that best-corrected acuity was below-normal (20/40 or worse) in nearly 90% of the children. Additional evidence for refractive amblyopia among astigmatic individuals has been reported in two Native American populations that have a high prevalence of astigmatism. Boniuk\(^7\) measured astigmatism $1$ D in 33% of 951 members of the Sioux Lookout tribe. Results of recognition acuity testing in 516 tribal members indicated that 15% did not achieve best-corrected acuity better than 20/40. Kershner and Brick\(^41\) reported 87% prevalence of astigmatism $1$ D among 57 fourth and fifth grade Tohono O’Odham children. Best-corrected acuity was worse than 20/20 in 16%, in comparison to 2% among fourth and fifth grade non-Native American children. More recently, we reported that 25% of 100 school-age Tohono O’Odham
children and adults without ocular pathology could not be refracted to 20/20 acuity. Song et al. examined best-corrected visual acuity in 152 eyes of three- to five-year-olds with astigmatism $1 \text{ D}$, and found evidence of amblyopia in a large portion of the children: 6% had visual acuity worse than 20/200, 36% had acuity between 20/200 and 20/67, 45% between 20/50 and 20/33, and only 13% had visual acuity of 20/29 or better. Although the preceding studies suggest that refractive amblyopia can be associated with astigmatism, data from Gwiazda et al. indicate that refractive amblyopia is not always present in individuals with MA. Gwiazda et al. reported MA of up to 2.5 octaves for vernier stimuli in a group of non-astigmatic children who had 20/20 recognition acuity and a history of astigmatism in infancy.

D. *Evolutionary and Ontogenetic Time Scales.* How much variability exists among individuals regarding the length of the sensitive period, and regarding the effects of astigmatism during the sensitive period on visual outcome? How much can the visual outcome of astigmatism present during the sensitive period be influenced by, for example, amount of astigmatism and timing of treatment?

As summarized above, only a small number of individuals with astigmatism-related amblyopia have been studied, probably due to the low prevalence of high astigmatism among typical urban school-age and adult populations. Therefore, data are limited concerning variability across individuals in the timing of the sensitive period for astigmatism-related amblyopia, and concerning variability in the effects of different types and amounts of astigmatism on visual development.

Evidence from studies of other types of amblyopia suggests that the amount of across-individual variability in the timing of the sensitive period depends on the underlying causes of the amblyopia. For example, the sensitive period for effective treatment of deprivation amblyopia caused by a dense unilateral cataract is very short, with few, if any, infants developing 20/20 acuity if surgery is delayed past age 6 weeks. In contrast, there is evidence that anisometropic amblyopia and bilateral isometropic amblyopia secondary to bilateral hyperopia can be effectively treated in school-age children, and improvement in anisometropic amblyopia has been documented in adults. As in anisometropic and isometropic amblyopia secondary to hyperopia, the amblyopia found in astigmatic individuals has an underlying cause that is refractive in nature. In addition, in many individuals, the astigmatism-related amblyopic deficit has been reported to be less than 1 octave in magnitude. These factors, plus a small number of case reports
indicating that the sensitive period for MA extends at least to age seven years, suggest that it is likely that the sensitive period for astigmatism-related amblyopia extends into the school-age years in at least some individuals.

Need for Further Research

In summary, research first presented 25 years ago indicates that uncorrected astigmatism during childhood can result in non-optical acuity deficits. Only limited data are available, however, concerning factors that influence the development and treatment of the non-optical acuity deficits. Furthermore, the timing and duration of the sensitive period during which uncorrected astigmatism can influence acuity development are not well defined.

A Study Population with a High Prevalence of Astigmatism

A high prevalence of large amounts of astigmatism has been documented among school-age and adult members of many Native American tribes. Studies of two of these tribes have reported an increased prevalence of below-normal best-corrected visual acuity, consistent with the presence of astigmatism-related amblyopia. Little information is known about the age at which astigmatism is typically first corrected in Native American children. However, data from one tribe, the Tohono O’Odham of southern Arizona, indicate that few astigmatic children receive glasses prior to grade school. Furthermore, as reported previously for astigmatic children of other tribes, astigmatic Tohono O’Odham grade school-aged children do not routinely wear glasses, even though the accepted practice among pediatric eye care practitioners is to correct astigmatism greater than about 1.5 D in young children. Thus, it is likely that a substantial number of Tohono O’Odham children have developed astigmatism-related amblyopia, and could serve as a subject pool for the study of the many unanswered questions about the development and treatment of this type of refractive amblyopia. Answers to questions about astigmatism-related amblyopia would not only increase scientific knowledge about sensitive periods, but could have a significant impact on the public health of Native American children of many tribes, both in improvement in vision and in potential improvement in school performance, which has been shown to be lower in astigmatic than in non-astigmatic Native American children.

In conclusion, objectives included in the report of the National Advisory Eye Council, Vision Research - A National Plan: 1999-2003, include studying the development of plasticity of neuronal mechanisms affected in amblyopia.
and the development of innovations in the detection and treatment of amblyopia. The following proposal to study astigmatism in children of the Tohono O’Odham Nation will provide important information on the development and treatment of astigmatism-related amblyopia, and will provide a valuable public health service for populations with a high prevalence of astigmatism.
2. OBJECTIVES AND OUTCOME MEASURES

Evidence from the scientific literature indicates that uncorrected astigmatism during childhood is associated with three types of amblyopia: (1) a difference in best-corrected acuity and contrast sensitivity for orthogonally-oriented gratings (meridional amblyopia or MA), (2) a difference in best-corrected acuity for orthogonally-oriented vernier acuity stimuli (also termed MA), and (3) a deficit in best-corrected recognition (letter) acuity. These data suggest the presence of a sensitive period for the development of astigmatism-related amblyopia. However, only limited information is available defining the parameters of the sensitive period for the development of astigmatism-related amblyopia, i.e. factors that influence the development and the responsiveness to treatment of astigmatism-related amblyopia.

The lack of research regarding astigmatism-related amblyopia is most likely due to the low prevalence of astigmatism in most populations of children. However, a high prevalence of large amounts of astigmatism and astigmatism-related amblyopia has been documented in members of the Tohono O’Odham Nation, a Native American tribe whose reservation is located in southern Arizona. In addition, research has indicated that the majority of highly astigmatic Tohono O’Odham grade-school children are not currently wearing eyeglass correction. The presence of this large sample of uncorrected highly astigmatic children provides a unique opportunity for the study of the development and treatment of astigmatism-related amblyopia.

The goals of the present study are:

A. To characterize vision deficits associated with astigmatism-related amblyopia in grade-school children.
B. To identify factors influencing the development of astigmatism-related amblyopia in grade-school children.
C. To determine age-specific effects of glasses intervention on astigmatism-related amblyopia in grade-school.

To achieve these primary goals, the following data collection and intervention procedures will be conducted:

C Subject recruitment, and collection of data regarding ophthalmic and glasses-wearing history.

C Cycloplegic refraction, and measurement of best-corrected distance recognition acuity, and best-corrected grating acuity, vernier acuity, and
contrast sensitivity for orthogonally-oriented stimuli prior to glasses intervention.

C Dispensing of glasses to children with astigmatism, followed by an intensive 3- to 5-week program to encourage compliance.

C Follow-up testing of best-corrected distance recognition acuity, and best-corrected grating acuity, vernier acuity, and contrast sensitivity for orthogonally-oriented stimuli 3 to 5 weeks after glasses dispensing.

C Follow-up testing of best-corrected distance recognition acuity, and best-corrected grating acuity, vernier acuity, and contrast sensitivity for orthogonally-oriented stimuli at one year after dispensing of glasses.

The design will address each of the three study goals in the following manner:

**C Goal 1:** Astigmatism-related amblyopia will be characterized through a comparison of best-corrected distance recognition acuity, and best-corrected grating acuity, vernier acuity, and contrast sensitivity for orthogonally-oriented stimuli prior to glasses intervention in astigmatic versus non-astigmatic Native American school-age children.

**C Goal 2:** The identification of factors related to the development of astigmatism-related amblyopia will be accomplished through analysis of the relation between optical factors (amount of astigmatism, location of anterior focal plane, age at first correction, and compliance with glasses wear), and each of four measures of best-corrected vision (distance recognition acuity, and grating acuity, vernier acuity, and contrast sensitivity for orthogonally-oriented stimuli).

**C Goal 3:** Evaluation of the effectiveness of glasses intervention on the reduction or elimination of astigmatism-related amblyopia in children of different ages and glasses wearing history will be based on an analysis of the improvement in each of four measures of best-corrected vision (distance recognition acuity, and grating acuity, vernier acuity, and contrast sensitivity for orthogonally-oriented stimuli) between the time of the initial study examination and two subsequent time points: (a) 3 to 5 weeks after dispensing of glasses and implementation of intensive measures to ensure compliance with glasses wearing, and (b) 1 year after dispensing of glasses. Additional factors to be considered in the analysis are age at first spectacle correction and consistency of spectacle wearing since first correction.
3. **PERSONNEL**

   **A. Duties**

   The project staff will include the principal investigator, co-investigators, project coordinator, project registrar, research assistant, secretary, and student assistant. In addition, two optometrists will be available as back-up testers. The duties of each member of the study team are outlined below.

   **Principal Investigator (PI) Erin M. Harvey**

   1. Ensure that the study is conducted according to the protocol described in this manual.
   2. Supervise all study personnel.
   3. Train study personnel along with the co-investigators (JMM and MVD).
   4. Oversee testing at elementary school sites.
   5. Work with Drs. Miller and Dobson to develop educational programs and materials to be presented at parent/teacher meetings and in classroom settings.
   6. Make educational presentations to parents, teachers, and children.
   7. Work with Drs. Sherrill, Miller, and Dobson during data analysis.
   8. Collaborate with Drs. Miller, Dobson, and Sherrill in writing manuscripts and reports related to the project.

   **Co-Investigator (Co-I) Joseph M. Miller**

   1. Serve as Medical Director of project, determine subject eligibility, and communicate findings to parents.
   2. Serve as liaison between the study and the Tribal Council, Tribal Health and Human Services Committee, Tribal Head Start Office, and the staff and medical personnel of the Indian Health Service, to ensure the continued success of the project.
   3. Work with Drs. Harvey and Dobson to develop educational programs and materials to be presented at parent/teacher meetings and in classroom settings.
   4. Make educational presentations to parents, teachers, and children.
   5. Conduct ophthalmic examinations of each child who participates in testing and write prescriptions for spectacles for children who have
high refractive errors, as defined by study protocol. Oversee and monitor instillation of cycloplegic drops.

6. Establish and maintain computer databases, and work with Drs. Harvey, Sherrill, and Dobson during data analysis.

7. Collaborate with Drs. Harvey, Dobson, and Sherrill in writing manuscripts and reports related to the project.

**Co-Investigator (Co-I) M. Velma Dobson**

1. Oversee the collection and analysis of all measures of visual acuity and contrast sensitivity used in the project.

2. Work with Drs. Harvey and Miller to develop educational programs and materials to be presented at parent/teacher meetings and in classroom settings.

3. Make educational presentations to parents, teachers, and children.

4. Train study personnel in the acuity and contrast sensitivity tests to be conducted.

5. Work with Dr. Harvey in maintaining high quality grating acuity, vernier acuity, and contrast sensitivity stimuli and test books.

6. Collaborate with Dr. Sherrill, Dr. Harvey, and Dr. Miller to develop and maintain a database that will permit easy longitudinal and cross-sectional analysis of visual acuity and contrast sensitivity data.

7. Participate in vision testing of children.

8. Oversee the analysis of acuity and contrast sensitivity results.

9. Work with Drs. Harvey, Sherrill, and Miller during data analysis.

10. Collaborate with Drs. Harvey, Miller, and Sherrill in writing manuscripts and reports related to the project.

**Co-Investigator (Co-I) Duane L. Sherrill**

1. Oversee the preparation of summary statistics and plots needed for interim reports and presentations to the Data Monitoring and Oversight Committee and at national meetings.

2. Participate in the writing of interim manuscripts and reports.

3. Supervise the preparation of final study analyses, advise the study group on the interpretation of study results, and participate in the writing of manuscripts based on final study results.
**Project Coordinator (PC) Irene Adams**

1. Conduct check-in, glasses re-fitting, and frame selection during Part A test sessions.
2. Conduct check-in, glasses fitting, and check-out during Part B.
3. Educate parents about the importance of glasses wearing.
4. Assist Dr. Harvey and Ms. Clifford in preparing for testing sessions.
5. Assist Dr. Harvey and Ms. Clifford in maintaining study equipment.
6. Organize and file study records related to glasses wearing.
7. Contact schools to schedule testing sessions and to schedule presentations at parent/teacher meetings and in classrooms in which children are scheduled to participate in study procedures.
8. Serve as a primary presenter of educational material at parent/teacher conferences and in classrooms.
9. Visit each classroom two times per week to monitor and encourage glasses wearing during the 3- to 5-week period between dispensing of glasses and follow-up testing. After the 3- to 5-week follow-up test session, visit the classroom once per month to continue to monitor and encourage glasses wearing, until the time of the one-year follow-up examination.
10. Re-fit and re-order glasses as needed.

**Project Registrar (PR) Frances Lopez**

1. Obtain consent from parents prior to and during testing sessions
2. During Part A testing sessions, get children from the classroom, return children to the classroom following instillation of dilating drops, and then, following 40 minutes of dilating time, bring the children back for cycloplegic refraction.
3. Serve as one of the visual acuity and stereopsis testers during Part A and Part B testing sessions.
4. Work with the Drs. Harvey, Miller, and Dobson and Ms. Adams to develop educational programs and materials to be presented at parent/teacher meetings and in classroom settings.
5. Assist the PC in presentation of material at parent/teacher meetings and in classroom settings.
6. Look up children’s IHS medical record numbers so that we can provide eye examination results to their physicians (for children for whom parental permission for release of data has been obtained).
Research Assistant (RA) Candice Clifford

1. Order study equipment and construction of vertical and horizontal grating acuity and vernier acuity booklets.
2. Conduct data entry and management of study files.
3. Prior to testing, enter into the study database the demographic and eye examination history of each child to be tested.
4. After each testing session, enter all data into the study database.
5. During the primary data collection period (Fall ’01 through Spring ’05):
   a. Work with Dr. Harvey and school personnel to schedule test sessions at each school.
   b. Ensure that all equipment and supplies needed for testing are available and in working order prior to each test session.
   c. Work with Dr. Harvey to coordinate the scheduling of personnel for each test session
6. Participate in testing of study participants during both Part A and Part B testing sessions.
7. Assist the Project Coordinator in fitting and distributing glasses, and in monitoring of compliance with glasses wearing.
8. During the summers, when no testing occurs, replace and repair study supplies and equipment.

Secretary/Back-up Tester Pat Broyles

1. Serve as secretary: prepare correspondence between study personnel and the Tribe, and type all manuscripts and study reports.
2. Be available, as needed, to conduct visual acuity testing during Part B testing sessions.
3. Assist in contacting schools to schedule and confirm testing sessions.

B. Training

Fall, 2000

Orientation Session: All study personnel will attend an orientation session in which the PI and Co-Is will present a summary of the background and significance of the AACDAT study, an overview of the study design and procedures, and a demonstration of testing techniques and materials to be used.
Review of Background Materials: Prior to training, all study personnel involved in testing (PI, Co-Is, PC, PR, RA, Secretary, and Optometrists) will read the Manual of Procedures (MOP).

Practice Testing Session: Once testing personnel have had an opportunity to practice with the test procedures, a practice session will be arranged. The session will take place at the Ophthalmology lab/office, and it will take place before the first testing session. The children who participate in the practice session will be volunteers from the Tucson area. Testing procedures will be conducted as described in the MOP. Eight to ten 6 to 10-year-old children will be scheduled at half-hour intervals (4-5 in the morning and 4-5 in the afternoon).

The goal will be to allow all personnel to practice letter acuity, grating acuity, vernier acuity and contrast sensitivity testing procedures.

Each step in the MOP protocol will be evaluated, and any additions or corrections will be made to improve clarity of the manual. Between morning and afternoon sessions, testing personnel will meet and discuss possible concerns, and the PI and Co-Is will provide feedback to the testers.
4. **TIME TABLE**

**2000/01 Academic Year**

**Fall**
Train personnel on letter acuity, grating acuity, vernier acuity, and contrast sensitivity testing procedures. Order supplies and equipment.

Meet with San Xavier Mission School principal and teachers and explain project to them. Begin recruiting subjects, obtaining informed consent.

Order/construct supplies and equipment.

PI develops computer database.

**Spring**
Test all children from San Xavier Mission School in *Part A* and *Part B* (initial) and *Part B* (follow-up).

**2001/02 Academic Year**

**Summer**
Meet with principals and teachers and explain project to them (San Simon, Baboquivari Intermediate, Santa Rosa Boarding, Santa Rosa Ranch Schools).

Begin recruiting 4-6th grade subjects, obtaining informed consent.

**Fall/Spring**
Test all 4-6th grade children in *Part A* and *Part B* (initial) and *Part B* (follow-up).

**Spring**
Test all children from San Xavier Mission School in 1 year-follow-up (*Part A* and *Part B*).

**2002/03 Academic Year**

**Fall/Spring**
Test all 5-7th grade children in 1 year follow-up (*Part A* and *Part B*).
2003/04 Academic Year

Summer Meet with principals and teachers and explain project to them (San Simon, Indian Oasis Elementary, Santa Rosa Boarding, Santa Rosa Ranch Schools)

Begin recruiting K-2rd grade subjects, obtaining informed consent.

Fall/Spring Test all K-2rd grade children School in Part A and Part B (initial) and Part B (follow-up).

2004/05 Academic Year

Fall/Spring Test all K-3rd grade children in 1 year follow-up (Part A and Part B).
5. **SUBJECTS**

A. **Eligibility**

Subjects will be elementary school children who attend elementary schools on the Tohono O’Odham reservation. Preliminary results from screening of children at these elementary schools indicate that approximately 42% have significant astigmatism ($1 \text{ D}$) in one or both eyes, and that only 14% of those with significant astigmatism are currently wearing glasses.\textsuperscript{16} Three cohorts of children will be recruited: a group of pilot subjects, an older cohort, and a younger cohort.

Occasionally, a child who is a Tribal member who is in the appropriate age range but not attending a school on the reservation will present and ask to participate. In the interest of good relations with the Tribe, these children will be tested and prescribed glasses (one pair per year) as indicated, but their data will not be included in the study.

**Pilot Subjects.** This cohort will consist of children who are in grades K-6 (n. 87) at San Xavier Mission School during the 2000-2001 school year. Testing of these children will permit us to develop protocols that minimize disruption of classroom activities, and will allow us to develop age-specific programs to maximize compliance with glasses wearing. Working out these details before we begin testing of the Older and Younger Cohorts will help to ensure standardization of protocol during collection of the primary study data.

**Older Cohort.** This cohort will consist of children who are in grades 4-6 (n. 396) during the 2001-2002 school year, excluding those who attend San Xavier Mission School (pilot subjects). This age group was selected because their participation in Head Start preceded our current study (AANAC), in which glasses are provided to Tohono O’Odham Head Start children who have high astigmatism. Prior to our current study, few preschool-age children received glasses for astigmatism. Therefore, astigmatic children in grades 4-6 during the 2001-2002 school year will be at-risk for astigmatism-related amblyopia. Children in grades 1-3 during the 2001-2002 school year should be at lower risk, since most students in grades 1-3 would have been in Head Start during our current study.

**Younger Cohort.** This cohort will consist of children who are in grades K-2 (n. 511) during the 2003-2004 school year. This age group was selected because their participation in Head Start will begin after the current (AANAC) study has been completed. These children will receive
screening through a program put in place by the current study, but getting a child to a follow-up examination and purchasing glasses will be left to the parents. Therefore, not all astigmatic children will have received glasses prior to entering school.

B. Recruitment

Recruitment of pilot subjects will occur during January 2001 (year 01 of the grant). Recruitment of subjects in the Older and Younger Cohorts will be conducted prior to the fall semester of the school year during which they will first be examined.

Parents will be sent a letter providing an overview of the study and request for participation, a consent form, a subject-information questionnaire concerning the child’s eye history, and a stamped return envelope for returning the consent form and questionnaire. The Project Registrar (PR) (tribal member), Project Coordinator (PC) (tribal member), and Research Assistant (RA) will follow up by phone or at parent-teacher meetings with parents who did not return the study forms.

We expect few parents to be present during testing, since testing will be conducted during school hours. Therefore, we will have to rely on parents to mail the consent forms to the school, to send the signed forms to school with the child, or to sign consent forms at parent-teacher meetings. The PR, PC, and RA will make reminder calls to parents about the forms, but some parents live in outlying areas and do not have a phone, and other parents may choose not to send in the forms.

C. Obtaining Ophthalmic and Glasses Wearing History

The primary eye history variables that are relevant to the study are:

- History of ocular pathology
- History of astigmatism
- Age at which child first received glasses
- Consistency of glasses wearing prior to entry into the study

Information on ophthalmic history will be obtained from four sources: the parent, the child, the child’s Indian Health Service (IHS) medical record (with parental consent, as documented in the study’s parental consent form), and Retinomax K+ autorefractometry results obtained during vision screening conducted at the child’s school or Head Start classroom during the AANAC study.
A questionnaire given to parents at the time of the child’s enrollment will include specific questions concerning the child’s previous glasses wearing and eye examination history (Appendix A). Historical data on presence of astigmatism will also be available from vision screening data collected during the current AANAC study. Non-cycloplegic refractive error data on all children attending the reservation’s six elementary schools were collected using the Retinomax K+ during the 1997-1998 and 1998-1999 school years (see Preliminary Results section). The results will provide historical data on astigmatism in Pilot Subjects in grades 3-6, and in children in the Older Cohort (grades 4-6). Historical data on astigmatism in subjects in the Younger Cohort (grades K-2) will be provided by Nidek KM500 autokeratometer data collected during Head Start vision screening that will be implemented beginning in the final year of the current study. Historical data on astigmatism in Pilot Subjects in grades K-2 will be available from Retinomax K+ data collected as part of the current AANAC study.

D. Informed Consent

1. Points to be Emphasized When Obtaining Consent

Informed consent will be obtained from the parent by going over the consent form of our project (Appendix A). The PR, a member of the Tribe who is fluent in the O’O’dham language, will go over the risks and benefits outlined in the consent form with the parent. When going through this form, the following points will be emphasized:

a. Participation in the project means that the child will be examined in Part A and Part B initial and Part B follow-up of the current year, and Part A and Part B initial in the following year. The consent applies all test sessions. This will save the parents the inconvenience of having to sign separate consent forms for each testing session. However, if the parent decides to withdraw the child from participating at any time, including in the midst of the first day’s examination, he or she is free to do so.

b. If the child is found to need glasses, the glasses will be provided and dispensed at school. The parents will be asked to help encourage the child to wear glasses, and to contact us if the glasses become lost or broken. We will also let the parents know that the teacher will be contacted routinely to make sure the glasses that were prescribed are being worn by the child.
c. The child will undergo pupil dilation on the first exam day (Part A) and again during the next school year, approximately one year later. We will explain to the parent the side effects to watch out for and provide them with a take-home letter (Appendix A) outlining what to watch for and how to contact the Principal Investigator should any symptoms arise.

d. Children will receive free eyeglasses and a free professional examination. The eyeglasses are of good quality. During the 1 year participation in the study, eyeglasses will be replaced as necessary due to normal breakage and wear-and-tear at no cost to the parents, and repairs will be made at no charge.

e. Parents receive no other remuneration for participation.

f. Professional services provided by the study include routine vision care for the one year of participation in study and treatment of any ill effects that may arise from participation in the project.

g. We are grateful for the participation of the Tribe and its members, and will do all that we can to ensure that participation is pleasant and enjoyable for the child. We will be available to answer any questions about the project.

We will have a one-hour training seminar at the beginning of each school year explaining to the teachers the protocol and the risks to the child. Personal contact will be made with each teacher during test days. A letter is provided to each teacher on the test day that provides a detailed listing of side effects.

2. **Rationale for Use of Dilating Eye Drops**

The use of dilating eye drops provides a simultaneous risk and benefit: risk of side effects associated with the medications used, but the benefit of an accurate measurement of refractive error.

The principal risks of participation are those related to the use of anesthetic and dilating eye drops. Our protocol of 0.5% Proparacaine followed by a drop of 1% Cyclopentolate and five minutes later by another drop of 1% Cyclopentolate is used to assure (1) adequate cycloplegia to permit accurate autorefraction to be obtained in this age group and (2) minimal pain or discomfort to the child.
Distance refractive error measurement requires that the subject’s accommodation be relaxed. This is best achieved by a combination of using eye drops to inhibit the ciliary muscle, use of fogging lenses, and use of a distance fixation target. Use of a distant fixation target and careful timing of autorefraction following administration of dilating drops provides optimum refractive error determination.

The selection of the autorefractor becomes important. Most studies of accommodation and refractive error have used the Canon R-1. The advantage this instrument provides over most others is a “head’s-up” display. That allows a distant fixation target to be viewed through a large beamsplitter. Such an instrument decreases the need for pharmacologic relaxation of accommodation, but is bulky and no longer commercially available.

The Nikon Retinomax K-Plus is a hand-held autorefractor with the fixation target buried inside the optical instrument. This prevents truly distant fixation targets from being used during refraction. The instrument does incorporate a fogging protocol, but pilot studies have identified that it is not completely reliable, and frequently subjects accommodate as a result of the psychological stimulus of the instrument being held near to their face (instrument myopia). It becomes important to maximize cycloplegia with this instrument to properly determine the full amount of hyperopia present.

Proper administration of eye drops provides the greatest single control of cycloplegia while minimizing the risk of undesired side effects. When an anesthetic drop is applied, and sufficient time given for the cornea to be anesthetized, reflex tearing to the stinging associated with Cyclogyl is minimized. By lifting the upper eyelid and allowing the drop of Cyclogyl to pool in contact with the cornea, corneal absorption is maximized. Most important is the careful administration of a single drop of the dilating agent, rather than flooding the fornix with the agent. The systemic effects arise from absorption through the nasolacrimal duct. Most of one drop will drain down the nasolacrimal duct, as the fornix has the capacity to hold far less than one drop. Any administration over the minimum will increase systemic absorption, which can produce undesired systemic toxicity. This is why it is important to administer the drops in a careful, controlled manner.

Should any adverse reactions be reported, the Principal Investigator will inform both the Data Monitoring and Oversight Committee.
members within one week, as well as the Human Subjects committee of the University of Arizona.

3. **Potential Risks Associated with Other Procedures**

There are no risks associated with the visual acuity testing protocol (letter acuity, grating acuity, vernier acuity, contrast sensitivity).

Finally, there is a risk of spectacle lenses interfering with the process of emmetropization. There is little hard data to guide us in the magnitude of this risk, but to minimize this risk, we will intentionally undercorrect the spherical component of hyperopia by up to one third or by 1D, whichever is greater, to provide a stimulus for emmetropization, for those subjects with significant hyperopia.
6. TESTING SESSIONS

A. Part A: Recognition Acuity Testing, Eye Examination, and Prescription of Glasses

The purpose of this part of the protocol is to determine the child’s “everyday” monocular recognition acuity, to measure the child’s refractive error, to check the child for ocular abnormalities, and to prescribe glasses, if needed. Study personnel required will be the PR, the PC, the RA, the eye care practitioner (JMM), and the PI (EMH, with Co-I VD as back-up). Procedures to be conducted are summarized in the following table.

<table>
<thead>
<tr>
<th>Task</th>
<th>Tester</th>
<th>Eye Tested</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check-In</td>
<td>PI and PC</td>
<td>N/A</td>
<td>1 min</td>
</tr>
<tr>
<td>Recognition Acuity and Stereo Acuity</td>
<td>RA and Co-I</td>
<td>RE and LE</td>
<td>7 min</td>
</tr>
<tr>
<td>(2 stations)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anterior Segment and Motility Exam</td>
<td>MD</td>
<td>RE and LE</td>
<td>1 min</td>
</tr>
<tr>
<td>Cycloplegic Drops - 1 min/drop</td>
<td>MD</td>
<td>RE and LE</td>
<td>7 min</td>
</tr>
<tr>
<td>+5 min wait</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Waiting Time</td>
<td>Child returns</td>
<td>N/A</td>
<td>40 min</td>
</tr>
<tr>
<td></td>
<td>to class</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Autorefraction</td>
<td>PI</td>
<td>RE and LE</td>
<td>1 min</td>
</tr>
<tr>
<td>Subjective Refinement, Fundus Exam</td>
<td>MD</td>
<td>RE and LE</td>
<td>5 min</td>
</tr>
<tr>
<td>Check-Out and Selection of Frames</td>
<td>PR and PC</td>
<td>N/A</td>
<td>1 min</td>
</tr>
</tbody>
</table>

Recognition Acuity and Stereo Acuity Assessment. Monocular recognition acuity will be assessed with the ETDRS\textsuperscript{19} letter acuity chart at a distance of 4 m. The chart will be mounted in a cabinet that provides back-illumination >10 cd/m\textsuperscript{2}. Children who have glasses will be tested with their glasses on. Each line on the ETDRS chart contains five letters. Beginning with the top line (20/200), the child will be asked to identify all five letters on each line of the chart, until he or she can no longer identify any of the five letters on a line. Visual acuity will be scored as the smallest line on which the child can correctly identify at least three of five letters. Acuity will also be evaluated using the letter-by-letter scoring method. If children are unsure of their letters, they will be given a lap card that contains all of the letters that appear on the chart, and will be asked to respond by matching the letters on the chart to the letters on the card. The ETDRS chart was selected because it is a logMAR chart that meets the
requirements of the Committee on Vision\textsuperscript{12} for assessment of visual acuity. In addition, it can be used successfully with grade school children, especially if younger children are provided with a lap chart for matching of letters.

Stereoaucuity will be assessed using the Randot Preschool Stereoaucuity Test (Stereo Optical Co., Chicago, IL), a commercially available clinical test of stereoaucuity that utilizes random dot stimuli in order to assess stereoaucuity in the absence of monocular depth cues. The stereoaucuity test includes six levels of retinal disparity that range from 800 to 40 seconds of arc, presented in three test books. For testing of stereoaucuity, subjects will wear specially-constructed polarized glasses. Beginning with the largest disparity level, subjects will be asked to identify shapes (e.g., star, house, duck) that appear in the random dot display. The random dot display is presented on the right side of the book, and the possible forms that can appear are shown in silhouette form on the left side of the book. Therefore, subjects can respond verbally or can point to the form on the left that they see in the random dot display on the right. Testing continues until a child is unable to correctly identify at least two shapes at a disparity level. Stereoaucuity is recorded as the smallest disparity at which the subject correctly identifies at least two of three shapes in the random dot display.

**Anterior Segment and Motility.** Children with manifest strabismus, nystagmus, or media opacity will be referred for further examination and their data will be excluded from study analyses.

**Instillation of Dilating Drops.** The MD or OD will instill one drop of 0.5% Proparacaine in each eye, followed by one drop per eye of 2% Cyclopentolate, followed 5 minutes later by one drop per eye of 1% Cyclopentolate. Children with a history of seizures will receive one drop per eye of 1% cyclopentolate in place of the one drop per eye of 2% cyclopentolate.

**Autorefraction, Subjective Refinement, and Fundus Examination.** Forty minutes after the first drops, autorefraction will be conducted by the PI, using the Nikon Retinomax K+ autorefractor. If the Retinomax K+ refractive astigmatism value for the right eye is $1 \text{ D}$ and if no other ocular abnormalities are detected during the eye examination, the child will be eligible for the astigmatic study group. If the Retinomax K+ cylinder value for the right eye is $0.75 \text{ D}$ and if no other ocular abnormalities are detected during the eye examination, the child will be eligible for the control (non-astigmatic) study group.
In addition to the Retinomax K+ measurement of cylinder, subjective refinement of sphere will be used to determine what glasses, if any, will be prescribed. The autorefraction measurement for each eye will be dialed into the phoropter, and the MD or OD will use subjective refinement of sphere to determine the spherical component of the best estimate of refractive error (BER). Thus, the BER will consist of the subjectively refined sphere and the autorefraction measurement of cylinder and axis. However, if the MD or OD judges that there is a difference in power >1.0 D along any meridian, the PI will take another autorefractor measurement and dial that into the phoropter. If the MD or OD judges that there is no difference in power >1.0 D along any meridian, the cylinder and axis of the second autorefraction measurement will be used in the BER. If the MD or OD again judges that there is a difference in power >1.0 D along any meridian, glasses will be prescribed if needed, based on the subjective refinement, but the child will not be eligible for further study participation. Use of the Retinomax K+ autorefractor to determine amount and axis of astigmatism will provide an objective measurement of the crucial study variable (astigmatism) and should not compromise adequacy of the glasses prescription, since Retinomax K+ values for astigmatism agree well with retinoscopic measurements of astigmatism in this population.38

For children who are too young to participate in the subjective refinement process, the MD or OD will record a confidence of 3 for refractive error measurement and the method used in the current AANAC study will be used to determine spectacle correction.47,50 Following autorefraction, the refractionist will use retinoscopy to obtain an independent measure of refractive error. If the retinoscopy measurement differs by #1.50 vector dioptric distance (VDD)33-35,38 from the first autorefraction measurement, the autorefraction measurement will be used as the BER. If retinoscopy differs by >1.50 VDD from the first autorefraction measurement, a second autorefraction measurement will be made. If the retinoscopy measurement differs by #1.50 VDD from the second autorefraction, the second autorefraction measurement will be used as the BER. If the difference again exceeds 1.50 VDD, a second retinoscopy measurement will be made. Then the measurement that is farthest from the vector dioptric mean of the four measurements will be discarded, and the vector dioptric mean of the remaining three measurements will be used as the BER. Typically, refractionists would use manual retinoscopy to measure refractive error in individuals who cannot participate in the refinement process. We propose to rely primarily on autorefraction instead, because it eliminates possible within- and between-retinoscopist bias in longitudinal estimates of refractive error. Furthermore, comparison of the results of three retinoscopists with Retinomax K+ results38 showed an average
difference between autorefraction and retinoscopy (0.75 VDD) that was less than previously-reported differences between two retinoscopy measurements on the same patient.59

Following subjective refinement, the MD or OD will examine the fundus of each eye using an indirect ophthalmoscope. If a child has optic nerve or other abnormalities that would be expected to interfere with vision, the child will be referred for further follow-up and the data will not be used in study analyses.

**Glasses Determination.** Glasses will be prescribed for any child who has $2.00 D of astigmatism in either eye and for any child whose uncorrected ETDRS acuity is worse than 20/20 in one or both eyes and whose BER in the eye(s) with worse than 20/20 acuity meets one or more of the following criteria:

- **C Astigmatism:** $1 D in either eye.
- **C Myopia:** $0.75 D on any meridian.
- **C Hyperopia:** $2.50 D on any meridian.
- **C Anisometropia:** >1.5 D spherical equivalent.

For astigmatism and myopia, the full correction will be prescribed. The hyperopic correction will be reduced by one-third or by 1 D, whichever is greater.26 Children who present already wearing glasses, even if their refractive error falls below the study threshold for prescribing glasses, will be maintained in spectacles using our BER, with the symmetrical decrease in hyperopia that we routinely apply. The glasses dispensed will be classified as control spectacles. The child will be identified as a member of the control group and will be tested wearing those glasses when he or she presents for the B test sessions. For the older cohort, two pair of glasses will be ordered for each child – a pair to be dispensed to the child, and a back-up pair to be kept by the PC until needed. For the younger cohort, three pair of glasses will be ordered for each child – a pair to be dispensed to the child, a pair to be dispensed to the teacher, and a back-up pair to be kept by the PC until needed.

**Check-Out.** If glasses are being prescribed, the PR or PC will explain to the child the reason for the glasses and will help the child pick out glasses frames.

**Post-Examination Follow-up.** A summary of the eye examination results will be sent to the parent/guardian of each child, along with a copy of the child’s eyeglass prescription, if glasses were prescribed.
B. **Part B: Dispensing of Glasses and Measurement of Best-Corrected Vision**

The primary purpose of Part B is to compare best-corrected vision in astigmatic versus non-astigmatic school-age children. Two groups of subjects will be tested: (a) Astigmatism Group: children who have astigmatism $\geq 1$ D with cylinder axis $\geq 75$ deg and $\leq 105$ deg in the right eye, as indicated by the autorefraction measurement in Part A (expected to be 35% of the population) and who were prescribed glasses (i.e., whose acuity was worse than 20/20 in one or both eyes), and (b) Control Group: children who have no astigmatism or astigmatism $<0.75$ D in both eyes, as indicated by the autorefraction measurement in Part A. Excluded from both groups will be children with ocular conditions that could affect monocular acuity, including anterior segment, motility, or fundus abnormalities, and anisometropia $>1.5$ D spherical equivalent (expected to be $<1\%$, based on complete eye examinations conducted on 379 Head Start children tested during the first two years of the current AANAC grant).

Eye examinations (Part A) will be conducted on a school-by-school basis. This will make it possible also to conduct Part B (dispensing of glasses and testing of best-corrected vision) on a school-by-school basis. Part B will be conducted as soon as glasses become available, approximately 2 to 3 weeks after glasses were prescribed (in Part A).

All children will be tested while wearing glasses. Those for whom glasses have been prescribed will be tested while wearing their own glasses (which will be dispensed by the PC and PI immediately before vision testing). Children who were not prescribed glasses will be fit with a pair of glasses in which the prescription for the right eye and the left eye differs by no more than 0.5 VDD$^{Harris-27-29,32}$ from their BER, as measured in Part A (above). To accomplish this, we will have a standard set of glasses with various prescriptions that would differ by $>0.5$ VDD from refractive errors in the range over which children would not be prescribed glasses ($<0.75$ D myopia, $<2.50$ D hyperopia), and would have cylinder correction $\leq 0.75$ D, which is a requirement for a subject’s inclusion in the control group. Because of the 3- to 5-week interval between refraction and testing, we will be able to ensure that a pair of glasses with appropriate correction will be available for each member of the control group.

Due to time constraints and limits on the attention span of some children tested (particularly the very young children), testing will be conducted for the right eye only (i.e., the left eye will be occluded with an eye patch), with the exception of distance letter acuity and stereoacuity. As
described in detail in chapter 7, in children with anisometropia (whose
data will be excluded from the primary analysis), testing will be
carried out on the eye with the worse ETDRS acuity, as measured during
the B session in which glasses are dispensed (the first B session).

Test order will be randomized across subjects for measures of letter acuity,
grating acuity, vernier acuity, contrast sensitivity, and stereoacuity. Each
subject will be randomly assigned a test order at the baseline vision testing
session (one of the 120 possible test orders that can be generated using 5
tests), and each subject will be tested in the same order at baseline and
at follow-up. This design was implemented to reduce the chance that
differences from baseline to follow-up within a measure of vision might be
obtained due to change in test order from baseline to 1 month and 1 year.

Testing will be conducted by the PC, PR, RA, and the Co-I, as indicated in
the following table.

<table>
<thead>
<tr>
<th>Task</th>
<th>Tester</th>
<th>Eye Tested</th>
<th>Test Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check-In, Glasses Fitting</td>
<td>PC and PI (EMH)</td>
<td>N/A</td>
<td>1 minute</td>
</tr>
<tr>
<td>Distance Letter Acuity*</td>
<td>PR, Co-I (VD), or RA</td>
<td>RE&amp;LE</td>
<td>3 minutes</td>
</tr>
<tr>
<td>Stereo Acuity*</td>
<td>PR, Co-I (VD), or RA</td>
<td>RE&amp;LE</td>
<td>2 minutes</td>
</tr>
<tr>
<td>Grating Acuity*</td>
<td>PR, Co-I (VD), or RA</td>
<td>RE</td>
<td>3 minutes</td>
</tr>
<tr>
<td>Vernier Acuity*</td>
<td>PR, Co-I (VD), or RA</td>
<td>RE</td>
<td>3 minutes</td>
</tr>
<tr>
<td>Contrast Sensitivity*</td>
<td>PR, Co-I (VD), or RA</td>
<td>RE</td>
<td>4 minutes</td>
</tr>
<tr>
<td>Check-Out</td>
<td>PC and PI (EMH)</td>
<td>N/A</td>
<td>1 minute</td>
</tr>
</tbody>
</table>

*Order of testing will be counterbalanced across subjects.

**Fitting of Glasses.** Before Part B is scheduled, the PI (EMH) will order the
glasses and will check to ensure that the glasses contain the correct
prescription. During Part B, the PI and PC will fit the glasses. This allows the
three vision testers to be masked to the refractive status of each child
during vision testing.

**Distance Letter Acuity.** As in Part A, monocular distance recognition
acuity will be tested using the ETDRS chart at a distance of 4 m. The
chart will be inserted in a cabinet that provides back-illumination so that
luminance is >10 cd/m². Acuity will be estimated using the letter-by-letter scoring method.

**Stereo Acuity.** As in Part A, stereo acuity will be tested with the random dot figures of the Preschool Randot Test.

**Grating Acuity.** Monocular grating acuity will be tested using a test book containing grating stimuli constructed from unmounted Teller acuity cards (Vistech, Inc, Dayton, OH), arranged in order of increasing spatial frequency. At each spatial frequency, pages containing vertical, horizontal, and oblique gratings will be included. The order of arrangement of grating orientation (vertical, horizontal, and oblique) will be the same for each spatial frequency, and will be counterbalanced across testing sites. Test distance will be 1.5 m. Each page of the test book will contain six 2.3/x 2.3/ targets, arranged in horizontal rows of three targets each. Within each row, one target will contain a grating stimulus, and the other two targets will contain a gray stimulus of equal space-averaged luminance, constructed from the gray portion of the Teller acuity card from which the grating target was cut. All grating targets on each page will be of the same spatial frequency and there will be two pages (a total of four rows) for each of the 13 spatial frequencies included in the book (from 38 to 0.86 cy/cm or 104 to 2.3 cy/deg, in approximately 0.5-octave steps).

Testing will start with the seventh spatial frequency (6.5 cy/cm), and the child will be required to identify the location (left, middle, or right, or #1, #2, or #3 as labeled) of the grating in the first row on the first page for each orientation within each spatial frequency. When the child incorrectly identifies the location of the gratings on a trial (any orientation), the tester will go back two spatial frequencies (wider stripes) for all three orientations. From then on the tester will require the subject to correctly identify the location of the grating on at least three of four trials for each orientation/spatial frequency before continuing on to the next highest spatial frequency for that orientation. If the child fails to identify grating location on three out of four trials for one orientation of a particular spatial frequency but correctly identifies grating location on three out of four trials on one or both of the other orientations, testing will progress to higher spatial frequencies only for those remaining orientations on which the child continues to correctly identify the grating location. Grating acuity for each line orientation will be scored as the highest spatial frequency stripes (finest stripe width) on which a child correctly locates the stripes on at least three of four trials. This procedure is similar
to the procedure used in our pilot study of vernier acuity, in which 100% of children were able to complete testing.

**Vernier Acuity.** Monocular vernier acuity will be tested using a test book containing vertical, horizontal, and oblique bars with and without vernier offsets, produced on a printer with a resolution of 600 dots/inch. At each vernier offset, one page containing vertical, one page containing horizontal, and one page containing oblique bars will be included. The order of arrangement of pages (vertical, horizontal, and oblique) will be the same for each vernier offset, and will be counterbalanced across testing sites. The test books will be similar to those used to test grating acuity; however, stimuli will be arranged in four columns on each page. Each column will contain three circular stimuli, two of which will contain bars without vernier offsets and one of which will contain a bar with vernier offsets. Test distance will be 1.75 m and 10 vernier offsets will be used. Vernier offsets will be the width of 1, 2, 3, 4, 6, 8, 11, 16, 23, and 32 dots on the printer. At the 1.75 m test distance, these offsets range from 5 arc sec to 120 arc sec, in approximately 0.5-octave steps. Starting with a page containing the largest offset, the child will be asked to identify which circle in the leftmost column contains a “wiggly” line. When the child incorrectly identifies the location of the “wiggly” line in the leftmost column on any of the grating orientations, the tester will go back two levels of vernier offset (larger offsets). The child will then be tested on 3 to 4 additional columns with that and subsequent vernier offsets. Vernier acuity will be estimated as the smallest offset at which the child correctly identifies the location of the vernier target on at least 3 of the 4 additional columns. This procedure was used successfully to test children in grades K-1 and 4-5 in our pilot studies, and is similar to that used successfully by Carkeet et al. to test children between 3 and 12 years of age.9,42

**Contrast Sensitivity.** Contrast sensitivity for horizontal and vertical stripes will be determined for three different grating spatial frequencies: 1.5, 6, and 18 cycles/degree at a test distance of 3 m. Stimuli will be constructed from a commercially available clinical test of contrast sensitivity, the VCTS6500 Contrast Sensitivity Chart (Vistech Consultants, Inc., LaSalle, IL). Within each of the three test books, there will be two pages at each contrast level. One page at each contrast level will contain vertical gratings and gratings that differ by 15 deg in a clockwise or counterclockwise direction from vertical, and the other page will contain horizontal gratings and gratings that differ by 15 deg clockwise or counterclockwise from horizontal. Order in which pages are arranged (horizontal first or vertical first) will be counterbalanced across test sites. The order in which books (i.e. spatial frequencies) are presented will be
counterbalanced across children, and each child will be tested in the same order at all B sessions. Within each book, each page will contain 4 stimuli at one contrast level, and pages will be organized in descending order of contrast level. Starting with the page containing the highest contrast level stimuli, the child will be asked to identify the orientation of the first grating on the page by rotating a pencil in front of them to the same orientation. When the child incorrectly identifies the first grating orientation on a page, the tester will go back two contrast levels. The child will then be tested on 3 to 4 additional gratings with that and subsequent contrast levels. If the child correctly identifies the orientation on at least 3 of the 4 gratings, the tester will continue with next lowest level of contrast. Testing will continue in this manner until a child is unable to identify at least 3 of 4 gratings on a page. Contrast sensitivity for that orientation/spatial frequency will be recorded as the lowest level of contrast on which the child was able to correctly identify at least 3 of 4 gratings. When threshold has been reached for both orientations in a book, the tester will proceed to the book containing the next spatial frequency for that child. This procedure is similar to that used to test children in our pilot study and is similar to that used successfully by other investigators to test contrast sensitivity to vertical gratings of 5 spatial frequencies in 5- to 7-year-olds.58,61

C. Distribution of Spectacles and Monitoring of Spectacle Wear

As indicated above, glasses will be dispensed at the beginning of Part B of the initial examination. At the end of Part B, we will provide teachers with a list of which children received glasses, and will remind teachers that the PC will visit the classroom two times per week for the next 3 to 5 weeks to check on compliance with glasses wearing, to encourage glasses wearing, and to adjust the fit of the glasses, if needed. Children will be encouraged to wear their glasses both at school and at home. If the glasses are lost or broken, the teacher or study staff will provide the child with replacement glasses, and study staff will order a back-up replacement pair that will be kept by the teacher or study staff (whoever gave the child the replacement pair).

A combined system of education and rewards will be used to encourage glasses wear. Educational activities will include a presentation by the PI, PR, PC, and Co-I (VD) at a parent-teacher meeting prior to dispensing of glasses, and an in-class educational presentation prior to the initial eye examination. Methods of encouragement for glasses wear will include a checkmark on the calendar at roll-call for older children.
After the first follow-up examination has been completed, the PC will make monthly visits to each classroom to provide adjustment for the eyeglasses and to monitor glasses wearing. These monthly visits will continue until the one-year follow-up examinations have been completed for children in that school. Approximately one-half of the children attend schools with year-round classes, which will permit study personnel to monitor glasses wearing in the classroom in the summer months. For the remaining children, glasses wearing in summer months will be monitored through phone calls and home visits (for families without phones). If a pair of glasses are lost or broken, the back-up pair will be given to the teacher and a new pair will be ordered and kept as a spare by the PC. Teachers and parents will be encouraged to contact the PR or PC as soon as glasses are lost or broken, so that a replacement pair can be ordered.

D. **Part B – Follow-up**

The effectiveness of short-term spectacle wearing in reducing astigmatism-related amblyopia will be assessed through vision testing conducted immediately following the 3- to 5-week intensive glasses-monitoring program. This time period is short enough to permit intensive monitoring and encouragement of glasses wearing, but is long enough to be within the time period (2 to 16 weeks) over which Moseley et al.\(^{55}\) found significant (mean = 0.21 log unit) improvements in acuity in the amblyopic eye of preschool- and school-age anisometropic amblyopes treated with spectacles only (prior to occlusion therapy). Improvement in best-corrected acuity after short-term spectacle wear is also recognized by the Amblyopia Treatment Study (ATS). The ATS protocol requires 4 weeks of spectacle wear to detect these short-term treatment effects. Short-term effects of glasses wearing have been observed by the Co-I (JMM), who participates in ATS and has had two subjects’ acuity improve significantly from spectacle wear alone, with the result that they were not eligible to be enrolled in the study.

Participants in follow-up testing will be (a) all children who had astigmatism $\geq 1$ D in the right eye at the initial examination and who received glasses, and (b) children (previously tested in Part B of the initial examination) who did not have astigmatism or who had astigmatism $<0.75$ D in both eyes at the initial examination.

Children will be tested in the same glasses as were worn for the test session conducted when glasses were dispensed (Part B, above). The testing protocol will be identical to that conducted in Part B, i.e., assessment of best-corrected recognition acuity of the right and left eyes and assessment of grating acuity, vernier acuity, and contrast sensitivity of the
right eye (or for anisometropic children, the eye with the worse ETDRS acuity at the first B session).
7. TESTING PROCEDURES

A. Part A: Recognition Acuity Testing, Eye Examination, and Prescription of Glasses

1. Order of Procedures

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</tr>
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2. Station 1A - Check-in (REG)

   a. Equipment
      - Lensmeter

   b. Procedure

      (1) During check-in, the PC will obtain consent from the parent or verify that a consent form one has been completed by a parent or guardian.

      (2) If the child is wearing glasses at check-in, the PI will use the lensmeter to check the glasses prescription and will write the results on the data sheet.

      (3) If child has history of reaction to eye drops, the PC or PI will write “no drops” on the eyedrops (Station 8A) data sheet.
c. **Data Sheet (Appendix B)**

The data sheet will be pre-printed with subject ID numbers, and will indicate whether consent was obtained prior to the test session. The PC will indicate consent obtained and history of reaction to dilation. If the child is wearing glasses, the prescription will be recorded on the data sheet.

3. **Station 2A – Screening ETDRS Acuity (SEA)**

a. **Equipment**
   - ETDRS symbols charts (Charts 1 and 2)
   - ETDRS flip cards
   - ETDRS lap card
   - Illuminated chart display cabinet
   - Pointer to point to the symbols or line
   - Measuring tape that is at least 4m long
   - Chair for the child
   - Eye patching tape

b. **Procedures**

   (1) Assemble, plug in, and turn on the chart display cabinet

   (2) Insert ETDRS Chart 1 into cabinet for testing of the right eye and Chart 2 for testing of the left eye.

   (3) Set up the chair so that it is 4m from the chart.

c. **Conducting the Test**

   (1) Have the child sit in the chair facing the chart, double check the distance from the child’s eyes to the ETDRS chart.

   (2) If the child wears glasses, test the child with the glasses on.

   (3) Explain to the child that you will show them a letter, and their job is to tell you the name of the letter.

   (4) The tester will hold the flip card 1-2 feet in front of the child, and present each of the letters. For each letter, the tester will ask the child to name the letter. If the child is able to identify each letter easily and consistently, the test may proceed with testing.
If the child has trouble identifying the letters, the tester should have the child try to match the letters on the flip chart to the letters on the lap card. If the child cannot do this, the tester should abandon ETDRS testing. [This step is done only for very young children.]

(5) The right eye should be tested first using Chart 1, and then the left eye should be tested using Chart 2. After the pretest with the flip cards is completed satisfactorily, the tester should put a patch over the left eye (micropore tape). The tester should explain that the patch does not hurt at all, and that we want to test what one eye can see all by itself.

(6) The tester will stand to the side of the ETDRS chart and point to the beginning of each line. If necessary to keep the child’s attention, the tester can point to individual letters with a pointer from below, in order to minimize interference with the crowding effect.

(7) The tester will begin with the top row, and begin presenting letters from left to right, moving down the chart until the child can no longer identify any letters. The tester should X incorrectly identified letters on the child’s data sheet. Continue down the chart until the child is unable to identify any of the 5 letters on a line.

(8) On the score sheet, circle the acuity value of the last line on which the child got at least 3 letters correct, and record tester's confidence in the acuity result (rated on a scale from 1-5. 1=low confidence that the acuity obtained reflects child’s true acuity (e.g., child was very distracted, inconsistent in responding), 5=very high confidence that the acuity obtained reflects the child’s true acuity (e.g., child was very cooperative and engaged in the task).

(9) Change to Chart 2 and proceed with testing of the left eye.

4. Station 3A - Testing Stereo Acuity (SAC)

a. Equipment
   C 3 Preschool Randot Test books with 40 cm ribbon attached to each
   C 2 pairs of Polaroid glasses (1 large, 1 small)
   C Extension cord
b. Preparation

(1) Put the examiner's and child's chairs next to the table.

(2) Arrange the Preschool Randot Test books on the table in the following order: Book 3 (800’/400”), Book 1 (200’/100”), Book 2 (60’/40”).

c. Conducting the Preschool Randot Test

(1) Have the child sit in the chair next to the table.

(2) Have the child put on one pair of the Polaroid glasses. If the child wears glasses, put the Polaroid glasses on over the child's glasses. If the child refuses to wear the glasses, record that the child was untestable.

(3) Do not open the test book until the child is wearing the Polaroid glasses. Monocular cues are apparent for some of the targets when the test plates in the test book are viewed without the Polaroid glasses in place.

(4) Open Book 3 and adjust its location so that it is 40 cm from the child. Use the 40 cm ribbon attached to the book to measure the distance.

(5) As a pretest, point to the top 4 panels on the non-stereo side of the book (black on white shapes) and ask “Can you point to the duck?” If incorrect/unable, stop the test and record Incorrect/Unable.

(6) If correct, continue testing with Book 3. Start with the set of stereo figures at the top of the page. For each figure, ask the child to identify the shape in each rectangle on the random dot page of the book. Mark the answers for the random dot side by circling correct responses and placing an “X” for incorrect responses (including no responses).

(7) If the child correctly identifies the location of at least 2 of the 3 stereo figures at the top of the page, continue testing with the set of figures at the bottom of the page.
(8) If the child correctly identifies the location of at least 2 of the 3 stereo figures at the bottom of the page, continue to test with first the top and then the bottom of Book 1.

(9) If the child correctly identifies the location of at least 2 of the 3 stereo figures at the top and bottom of the page in Book 1, continue to test with first the top and then the bottom of Book 2.

(10) If 2 of 3 are incorrect at one level, stop the test. There is no need to show the 3rd shape if 2 of 3 are both correct or both incorrect.

(11) Circle the smallest disparity level at which the child correctly identified at least 2 of the 3 stereo figures, and indicate the tester's confidence in stereo acuity results.

5. **Station 4A - Pupils, Anterior Segment and Motility (ANT)**

   a. **Equipment**
      
      - Direct ophthalmoscope
      - Finoff transilluminator
      - Finger puppets

   b. **Procedure**
      
      (1) Check direct and consentual pupil response using the Finoff transilluminator on high.

      (2) Check for presence of phoria or tropia performing standard cover test while the child views a distant fixation target.

      (3) Perform cover test for near phoria or tropia while subject views the finger puppet at near.

      (4) Use the direct ophthalmoscope to perform a red reflex test, looking for any evidence of cataract.

      (5) Examine each eye carefully with the direct ophthalmoscope for any anterior segment anomalies.

   c. **Data Sheet (Appendix B)**
      
      For each eye, pupils and anterior segment will be scored as normal (“pass”) or abnormal (“fail”). Motility will be scored as pass or fail.
Phorias are a “pass” but noted in the comment field. Tropias (manifest or intermittent) are scored as fails.

6. Station 5A - Cycloplegic Drops (GTT)

a. Equipment
   - Chair for the child
   - Tissues
   - Antiseptic handwipes
   - Bottle of 0.5% Proparacaine (red bottle)*
   - Bottle of 1.0% cyclopentolate (blue bottle)*
   - Digital clock

*Note: Date bottles when opened, they are good for 90 days after opening

b. Procedure

(1) If child has history of reaction to eye drops, do not give them! “No drops” will be written on the child’s Station 8A data sheet.

(2) Drops will be administered in the following order: RED (Proparacaine), followed 60 seconds later by BLUE (1% Cyclopentolate), followed 3 to 5 minutes later by BLUE (1% Cyclopentolate).

(3) Seat the child comfortably in the chair.

(4) Explain to the child that you will be putting two drops in each eye. The drop will sting for a few seconds, but then it will stop. The second drop will not hurt at all.

(5) Tilt the child’s head back.

(6) Grasp the top and bottom eyelids with fingers. Brace the other hand on the child’s forehead and instill 1 drop of Proparacaine in each eye (red bottle), and wipe excess drop or tears with a tissue. An assistant may help in holding the child’s head back, or holding the child’s eyelids.

(7) Sixty seconds after instillation of Proparacaine (RED), instill 1 drop of Cyclopentolate 1% (BLUE) in each eye (except as noted above), while pressing finger on the subject’s lower punctum to
minimize systemic absorption, and wipe any excess drop or tear on the cheek with a tissue.

(8) Record the time of the first two drops.

(9) Instill 1 drop of cyclopentolate 1% (BLUE) in each eye after 5 minutes.

(10) Record the time of the third drop.

(11) Give the child sunglasses.

c. **Data Sheet (Appendix B)**

Record the time of instillation of the drop of Proparacaine, the strength of the first drop of cyclopentolate and the time of instillation, and the strength of the second drop of cyclopentolate and the time of instillation of the second drop.

7. **Station 6A - Cycloplegic Retinomax Autorefraction and Measurement of Interpupillary Distance (CRM)**

a. **Equipment**
   - Pupillometer
   - Nikon Retinomax K+ Autorefractor (Rmax)
   - Chair for the tester and a chair for the child
   - Two Nikon Model Eyes (prior to testing any children, measurements of each model eye should be obtained in order to verify calibration of the Rmax)

b. **Procedure**

   (1) Have the child sit in a chair with his/her back against the backrest.

   (2) The tester should sit in a chair in front of and facing the child.

   (3) Turn on the Rmax, extend the forehead rest, press “mode” until “ref” and “ker” are illuminated, press R/L until the “R” is illuminated for measurement of right eye, be sure that ‘quick’ is not illuminated.

   (4) Tell the child to look in the little hole in front of the Rmax and see if they can find a picture.
(5) Look in the viewfinder. The display should indicate R0/L0 for refraction and R0/L0 for keratometry. This indicates that the Rmax has 0 measurements for right and left eyes. If it does not indicate this, reset the Rmax by turning it off and on again, and adjusting the modes as indicated above.

(6) Align the Rmax in front of the child’s right eye, and then look through the viewer. Center the display over the pupil, and adjust the distance so that the mire ring is as small and sharp as possible. It may help to place your free hand on top of the child’s head, to reduce movement and head tilting. Press the button on the handle to begin measurements.

(7) Encourage the child to keep looking in the Rmax.

(8) Once the Rmax display indicates that it has taken 8 refraction and 8 keratometry measurements (R8/L0), remove the Rmax from the child’s forehead, press “R/L” to illuminate “L” for measurement of left eye, and repeat procedure with the left eye.

(9) When right and left eye measurements are complete (refraction and keratometry should read R8/L8), aim the Rmax at the printer, and press the “print” button to print the child’s results.

(10) Tape the printout the child’s data sheet, and record the child’s sticker and name.

(11) Turn off the Rmax to clear the measurements for the next child.

(12) Use the pupillometer to measure interpupillary distance.

c. Data Sheet (Appendix B)

Record interpupillary distance. Rmax printouts will be attached with tape to the child’s preprinted data sheet. The time at which each Rmax reading was taken will be recorded.

8. Station 7A - Cycloplegic Subjective Refinement and Fundus Exam (CSR)

a. Equipment
   C Retinoscope
   C Phoropter
   C Letter acuity chart for display of letters at a distance of 10 feet
b. Procedure

(1) Subjective Refinement Procedure

(a) Subjective refinement of the autorefraction measurement obtained in station 6A will be used as the child’s “best estimate of refractive error” (BER).

(b) The autorefraction measurement for each eye will be dialed into the phoropter, and the MD or OD will use subjective refinement of sphere to determine the spherical component of the BER but use autorefraction to define cylinder and axis. Thus, the BER will consist of the subjectively refined sphere and the autorefraction measurement of cylinder and axis.

(c) When the child sits behind the phoropter, the retinoscopist will first set the phoropter to “R,” dialing in a +1.50 lens. Then, the streak will be swept in all meridia while the retinoscopist leans in and out to determine if neutrality has been achieved.

If neutrality is present, the retinoscopist may then adjust the sphere under the child’s direction to obtain best vision, and the BER and glasses prescriptions are based upon subjective sphere and autorefraction cylinder and axis. However, for glasses prescriptions, if both sphere powers are positive, up to 0.75 diopters of plus power will be symmetrically cut from the refraction. Small, asymmetric plus sphere corrections will be decreased by the value of the better sphere.

(d) If neutrality is not present, set the intercept to the axis with greatest motion, and then change the sphere dial until neutrality is achieved. If more than four clicks (1 D) of sphere change is needed to neutralize the streak, indicating disagreement of cylinder axis and power, a second autorefraction is needed.

If the MD or OD then judges that there is no difference in power > 1.0 D between the second autorefraction reading

7.9
and subjective refinement along any meridian, the retinoscopist may then adjust sphere under the child’s direction to obtain best vision.

The BER and glasses prescriptions are based upon subjective sphere and autorefraction cylinder and axis. However, for glasses prescriptions, if both sphere powers are positive, up to 0.75 diopters of plus power will be symmetrically cut from the refraction. Small, asymmetric plus sphere corrections will be decreased by the value of the better sphere.

(e) If the MD or OD again judges that there is still a difference in power >1.0 D along any meridian using the second autorefraction, glasses will be prescribed if needed, based on the subjective refinement, but the child will not be eligible for further study participation.

(f) For children who are too young to participate in the subjective refinement process, the method used in the current AANAC study will be used to determine spectacle correction (a computer program in which refraction values can be entered is used to calculate BER). This program works as follows:

Following autorefraction, the refractionist will use retinoscopy to obtain an independent measure of refractive error.

If the retinoscopy measurement differs by >1.50 vector dioptic distance (VDD) from the first autorefraction measurement, the autorefraction measurement will be used as the BER.

If retinoscopy differs by >1.50 VDD from the first autorefraction measurement, a second autorefraction measurement will be made. If the retinoscopy measurement differs by >1.50 VDD from the second autorefraction, the second autorefraction measurement will be used as the BER.

If the difference again exceeds 1.50 VDD, a second retinoscopy measurement will be made. Then the measurement that is farthest from the vector dioptic mean
of the four measurements will be discarded, and the vector
dioptric mean of the remaining three measurements will be
used as the BER.

(g) Once the MD or OD has arrived at the final BER, the
refraction is recorded on the child’s data sheet, along with
the child’s first name and sticker number.

(2) Fundus Examination Procedure

(a) The indirect ophthalmoscope is used to visualize each optic
nerve, as well as the posterior pole of the eye. Any
abnormality is recorded, and referred for subsequent
evaluation.

(b) Record whether the child passed or failed the fundus
examination. If the child fails, record the reason for failure in
the comments section.

9. Station 8A - Check-out (BYE)

Give parent the thank you/drops information letter if they are present,
and tell parent whether child will be getting glasses. Assist the child and
parent in selecting a pair of eyeglass frames. Explain dispensing of glasses
and care of glasses. If the parent is not present, a the thank you/drops
letter and a letter indicating whether or not glasses were prescribed will
be given to the child/teacher to send home to the parent (see Appendix
for letters).

B. Part B: Dispensing of Glasses and Measurement of Best-Corrected Vision

1. Order of Procedures

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<td>3</td>
<td>Stereo Acuity*</td>
</tr>
<tr>
<td>4</td>
<td>Grating Acuity*</td>
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<td>5</td>
<td>Vernier Acuity*</td>
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<td>6</td>
<td>Contrast Sensitivity*</td>
</tr>
<tr>
<td>7</td>
<td>Check-Out</td>
</tr>
</tbody>
</table>

*Order of testing (stations 2-6) will be counterbalanced across subjects
Testing of Anisometropic Subjects

As indicated above (first paragraph of section B on page 6.6), data from children who have anisometropia will not be included in the primary data analysis, because the difference in refractive error between eyes could affect monocular acuity development, resulting in unilateral amblyopia. However, as a side analysis, we would like to determine whether wearing glasses has a beneficial effect on acuity in children with unilateral amblyopia. Therefore, the following procedure will be used in Part B testing sessions for children who meet the study criterion for anisometropia: >1.50 D spherical equivalent difference in refractive error between eyes. The procedure will also be used for children who have significant astigmatism ($1.00 D cylinder) in the left eye but not in the right eye, since these children may also be at risk for unilateral amblyopia. Children who have significant astigmatism in the right eye but not in the left eye are included in the astigmatism group.

Procedure: Any child whose BER from Part A shows a difference between eyes >1.50 D spherical equivalent, or astigmatism in only one eye that is $1.00 D, will have ETDRS acuity measured first, prior to any other tests of visual function, in the Part B1 session. If there is a difference in ETDRS acuity between eyes, then all subsequent vision testing during Part B1 and Part B2 sessions will be conducted on the eye with the worse ETDRS acuity at the Part B1 session. If acuity is equal in the two eyes at the Part B1 session, then all subsequent vision testing will be conducted on the right eye, as is the case for all other study participants.

2. *Station 1B - Check-in (REG)*

a. **Equipment**

  - Lensmeter
  - Eyeglasses for children who were prescribed glasses in Part A
  - Set of numbered stock glasses for use by children who were not prescribed glasses in Part A.
  - List of children scheduled for testing, and summary of their BER and for children who were not prescribed glasses, the stock frame number that contains the appropriate prescription to be used for testing ($\#1.50 VDD$ from the child's BER).

b. **Procedure**

  (1) A summary printout will be generated that will list the children to be tested, verify that written informed consent was obtained, and
indicate the eyeglass correction that the child will wear during Part B testing.

(2) If the child is wearing glasses at check-in, the PI will use the lensmeter to check the glasses prescription and will write the results on the data sheet.

(3) Each child will be fit with a pair of eyeglasses. Children who were prescribed eyeglasses based on the Part A examination will fit with the pair of glasses that were ordered for him/her after Part A. Children who were not prescribed glasses will be fit with a pair of glasses from our stock in which the right eye and left eye correction is within (#) 0.50 VDD of the child’s correction (as determined by Part A).

c. Data Sheet (Appendix B)

The data sheet will be pre-printed with subject ID numbers, and will indicate whether consent was obtained prior to the test session. If the child is wearing glasses, the prescription will be recorded on the data sheet.

3. Station 2B – Corrected ETDRS Acuity (CEA)

a. Equipment
   - ETDRS symbols charts (Charts 1 and 2)
   - ETDRS flip cards
   - ETDRS lap card
   - Illuminated chart display cabinet
   - Pointer to point to the symbols or line
   - Measuring tape that is at least 4m long
   - Chair for the child
   - Eye patching tape

b. Procedures

   (1) Assemble, plug in, and turn on the chart display cabinet

   (2) Insert ETDRS Chart 1 into cabinet for testing of the right eye and Chart 2 for testing of the left eye.

   (3) Set up the chair so that it is 4m from the chart.
c. Conducting the Test

(1) Have the child sit in the chair facing the chart, double check the distance from the child’s eyes to the ETDRS chart.

(2) If the child wears glasses, test the child with the glasses on.

(3) Explain to the child that you will show them a letter, and their job is to tell you the name of the letter.

(4) The tester will hold the flip card 1-2 feet in front of the child, and present each of the letters. For each letter, the tester will ask the child to name the letter. If the child is able to identify each letter easily and consistently, the test may proceed with testing. If the child has trouble identifying the letters, the tester should have the child try to match the letters on the flip chart to the letters on the lap card. If the child cannot do this, the tester should abandon ETDRS testing. [This step is done only for very young children.]

(5) The right eye should be tested first using Chart 1, and then the left eye should be tested using Chart 2. After the pretest with the flip cards is completed satisfactorily, the tester should put a patch over the left eye (micropore tape). The tester should explain that the patch does not hurt at all, and that we want to test what one eye can see all by itself.

(6) The tester will stand to the side of the ETDRS chart and point to the beginning of each line. If necessary to keep the child’s attention, the tester can point to individual letters with a pointer from below, in order to minimize interference with the crowding effect.

(7) The tester will begin with the top row, and begin presenting letters from left to right, moving down the chart until the child can no longer identify any letters. The tester should X incorrectly identified letters on the child’s data sheet. Continue down the chart until the child is unable to identify any of the 5 letters on a line.

(8) On the score sheet, circle the acuity value of the last line on which the child got at least 3 letters correct, and record tester’s confidence in the acuity result (rated on a scale from 1-5. 1= low confidence that the acuity obtained reflects child’s true acuity (e.g., child was very distracted, inconsistent in responding), 5=very high confidence that the acuity obtained reflects the child’s true acuity (e.g., child was very cooperative and engaged in the task).
(9) Change to Chart 2 and proceed with testing of the left eye.

4. **Station 3B - Stereo Acuity (SAC)**

   a. **Equipment**
      - C3 Preschool Randot Test books with 40 cm ribbon attached to each
      - C2 pairs of Polaroid glasses (1 large, 1 small)
      - CExtension cord
      - CSmall table
      - CChair for examiner, chair for child

   b. **Preparation**
      
      (1) Put the examiner’s and child’s chairs next to the table.
      
      (2) Arrange the Preschool Randot Test books on the table in the following order: Book 3 (800”/400”), Book 1 (200”/100”), Book 2 (60”/40”).

   c. **Conducting the Preschool Randot Test**
      
      (1) Have the child sit in the chair next to the table.
      
      (2) Have the child put on one pair of the Polaroid glasses. If the child wears glasses, put the Polaroid glasses on over the child’s glasses. If the child refuses to wear the glasses, record that the child was untestable.
      
      (3) **Do not open the test book until the child is wearing the Polaroid glasses.** Monocular cues are apparent for some of the targets when the test plates in the test book are viewed without the Polaroid glasses in place.
      
      (4) Open Book 3 and adjust its location so that it is 40 cm from the child. Use the 40 cm ribbon attached to the book to measure the distance.
      
      (5) As a pretest, point to the top 4 panels on the non-stereo side of the book (black on white shapes) and ask “Can you point to the duck?” If incorrect/unable, stop the test and record Incorrect/Unable.
(6) If correct, continue testing with Book 3. Start with the set of stereo figures at the top of the page. For each figure, ask the child to identify the shape in each rectangle on the random dot page of the book. Mark the answers for the random dot side by circling correct responses and placing an “X” for incorrect responses (including no responses).

(7) If the child correctly identifies the location of at least 2 of the 3 stereo figures at the top of the page, continue testing with the set of figures at the bottom of the page.

(8) If the child correctly identifies the location of at least 2 of the 3 stereo figures at the bottom of the page, continue to test with first the top and then the bottom of Book 1.

(9) If the child correctly identifies the location of at least 2 of the 3 stereo figures at the top and bottom of the page in Book 1, continue to test with first the top and then the bottom of Book 2.

(10) If 2 of 3 are incorrect at one level, stop the test. There is no need to show the 3rd shape if 2 of 3 are both correct or both incorrect.

(11) Circle the smallest disparity level at which the child correctly identified at least 2 of the 3 stereo figures, and indicate the tester’s confidence in stereo acuity results.

5. **Station 4B – Corrected Grating Acuity (CGA)**

a. **Equipment**

- 2 books of grating stimuli, ordered from largest (Book 1, 2.6 to 9.6 cy/deg) to smallest (Book 2, 14.4 to 114 cy/deg), spatial frequencies, with horizontal, vertical, and oblique gratings presented sequentially at each spatial frequency, according to the order determined for the school where testing will occur
- Chair for the tester and a chair for the child
- Measuring ribbon 1.5 m long attached to each book
- Light meter
- Clip lamp with extra bulbs
- Extension cord
- Table
b. Set Up

(1) Set up the child’s chair 1.5 m from the tester’s chair.

(2) Check the lighting with the light meter, use the clip lamp to adjust the lighting so that it is even across cards and above the 5 tick mark on the light meter (above 10 cd/m²).

(3) Sit in the tester’s chair and place Book 2 on the table.

c. Procedure

(1) The child should be seated with his/her eyes 1.5 m from the cards, as measured by the ribbon attached to the book.

(2) Explain to the child that he/she will be playing a ‘stripes’ game. His/her job is identify which one of 3 circles contains stripes.

(3) Before testing, make sure that the eyeglasses fit correctly and comfortably on the child, and that the left eye is occluded with a piece of micropore tape underneath the eyeglasses. Only the right eye will be tested with grating acuity stimuli (unless the child is anisometric and ETDRS acuity was worse in the left eye than in the right eye).

(4) All grating targets on each page will be of the same spatial frequency and there will be two pages (2 horizontal rows) for each orientation of each of the 12 spatial frequencies included in the book (from 38 to 0.86 cy/cm or 114 to 2.6 cy/deg, in approximately 0.5-octave steps). Each page of the test book will contain six 2.3/ x 2.3/ targets, arranged in horizontal rows of three targets each. Within each row, one target will contain a grating stimulus, and the other two targets will contain a gray stimulus. Starting with the lowest spatial frequency in Book 2 (19.5 cy/deg), ask the child to identify the location (1, 2, or 3) of the grating in the top row on the first page for each orientation at each spatial frequency. When the child incorrectly identifies the grating location, the tester will go back two spatial frequencies (the spatial frequency one octave lower than that incorrectly identified). The child will then be tested on 3 to 4 additional rows with that and subsequent spatial frequencies. Acuity will be estimated as the finest grating on which the child correctly identifies the location of the grating on at least 3 of the 4 additional rows for each orientation.
(5) If the child cannot identify the location of the grating for at least one orientation of the lowest spatial frequency gratings in Book 2, the tester should go to Book 1 and begin testing with the lowest spatial frequency gratings in Book 1.

(6) Once testing for the first stripe orientation is completed, the grating acuity result should be recorded. Testing continues for the remaining orientations until threshold for each is reached.

d. Data Sheet (Appendix B)

Record child’s encounter number, first name, the acuity for horizontal gratings (grating number), confidence in horizontal acuity result, the acuity for vertical gratings (grating number), the confidence in the vertical acuity result, the acuity for oblique gratings (grating number), and the confidence in the oblique acuity result.

6. Station 5B – Corrected Vernier Acuity (CVA)

a. Equipment

C Book of vernier stimuli, ordered from largest to smallest offset size (10 total offset sizes), with horizontal, vertical, and oblique gratings presented sequentially at each spatial frequency, according to the order determined for the school where testing will occur
C Chair for the tester and a chair for the child
C Measuring ribbon 1.75 m long, attached to test book
C Light meter
C Clip lamp with extra bulbs
C Extension cord
C Table

b. Set Up

(1) Set up the child’s chair 1.75 m from the tester’s chair.

(2) Check the lighting with the light meter, use the clip lamp to adjust the lighting so that it is even across cards and above the 5 tick mark on the light meter (above 10 cd/m²).

(3) Sit in the tester’s chair and place the book of stimuli on your lap.

c. Procedure

(1) The child should be seated with his/her eyes 1.75 m from the cards, as measured by ribbon attached to book.
(2) Explain to the child that he/she will be playing a game and that his/her job is identify which one of 3 lines is “wiggly.”

(3) Before testing, make sure that the eyeglasses fit correctly and comfortably on the child, and that the left eye is occluded with a piece of micropore tape underneath the eyeglasses. Only the right eye will be tested with vernier acuity stimuli (unless the child is anisometropic and ETDRS acuity was worse in the left eye than in the right eye).

(4) All vernier targets on each page will be of the same offset and there will be one page (4 vertical columns) for each orientation of each of the 10 vernier offsets. Each of the 4 columns on each page will include three circular stimuli, two of which will contain two bars without vernier offsets and one bar with vernier offsets. The child will be asked to identify which circle contains a “wiggly” line. (Vernier offsets will be the width of 1, 2, 3, 4, 6, 8, 11, 16, 23, and 32 dots on the printer. At the 1.75 m test distance, these offsets range from 5 arc sec to 120 arc sec, in approximately 0.5-octave steps.) Starting with the largest offset, the child will be required to identify the location (top, middle, or bottom) of the “wiggly” line in the first column on the first page for each orientation of each spatial frequency. When the child incorrectly identifies the vernier stimulus location, the tester will go back two offset sizes. The child will then be tested on 3 to 4 additional columns with that and subsequent offsets. **Acuity will be estimated as the smallest vernier offset on which the child correctly identifies the location of the vernier stimulus on at least 3 of the 4 additional columns for each orientation.**

(5) Once testing for the first vernier orientation is completed, the vernier acuity result should be recorded. Testing continues for the remaining orientations until threshold for each is reached.

d. **Data Sheet (Appendix B)**

Record the acuity for horizontal vernier stimuli, confidence in horizontal vernier acuity, the acuity for vertical vernier stimuli, the confidence in the vertical vernier result, the acuity for oblique vernier stimuli, and the confidence in the oblique vernier result.
7. **Station 6B – Corrected Contrast Sensitivity (CCS)**

a. **Equipment**
   - 3 contrast sensitivity test books, one for 1.5 cy/deg, one for 6 cy/deg, and one for 18 cy/deg
   - Chair for the child, chair for the tester
   - A pen for the child to use to indicate line orientation
   - Measuring tape at least 3 m long
   - Light meter
   - Clip lamp with extra bulbs
   - Extension cord
   - Counterbalanced order data sheets

b. **Set Up**

(1) Place the Contrast Sensitivity chart on your lap, and set up the child’s chair 3 m from the book.

(2) Check the lighting with the light meter, use the clip lamp to adjust the lighting so that it is even across book and above the 5 tick mark on the light meter (above 10 cd/m²).

c. **Procedure**

(1) The child should be seated with his/her eyes 3m from the book.

(2) Explain to the child that he/she will be playing a game and that his/her job is hold the pen up in the orientation that matches the orientations of the lines on the chart.

(3) Before testing, make sure that the eyeglasses fit correctly and comfortably on the child, and that the left eye is occluded with a piece of micropore tape underneath the eyeglasses.

(4) Contrast sensitivity for vertical and horizontal gratings will be tested at three different spatial frequencies (1.5, 6, and 18 cy/deg). Each test book contains 8 contrast levels of a single spatial frequency, with horizontal and vertical gratings presented sequentially at each contrast level. Each page will contain 4 stimuli at the same level of contrast, starting with the highest contrast, and continuing to the final page of the section, which will contain horizontal and vertical stimuli at the lowest contrast level of that spatial frequency. Starting with the highest contrast level, the child will be asked to identify the orientation of the first grating on the page by rotating a pencil in front of them to the same orientation. When the child incorrectly
identifies the grating orientation, the tester will go back two contrast levels. The child will then be tested with 3 to 4 stimuli on each page. If the child correctly identifies the orientation on at least 3 of the 4 gratings, the tester will continue with the next page. Testing will continue in this manner until a child is unable to identify at least 3 of 4 gratings on a page for an orientation. When this threshold is reached, contrast sensitivity for that orientation/spatial frequency is recorded as the lowest level of contrast on which the child was able to correctly identify at least 3 of 4 gratings. Testing continues on the remaining orientation until the child is unable to identify at least 3 of 4 gratings on a page for that orientation.

(5) The tester should check the counterbalancing order sheet before testing to determine which spatial frequency should be used first, which should be used second, and which should be used third.

d. Data Sheet (Appendix B)

Record the contrast threshold for vertical and horizontal orientations for each spatial frequency and the confidence for each of the six contrast sensitivity results.

8. Station 7B - Check-out (BYE)

After completion of all testing, children who were prescribed glasses will meet with the PC, who will explain to them how to take care of their eyeglasses, and instruct them that they should wear their glasses both at home and at school. For children who were not prescribed glasses, the stock pair of eyeglasses will be collected and cleaned at the end of the session.

C. Part B – Follow-up: Measurement of Best-Corrected Vision

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<tr>
<th>Order of Procedures</th>
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<tr>
<td><strong>Test Station</strong></td>
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<tr>
<td>1</td>
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<tr>
<td>2</td>
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<td>7</td>
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*Order of testing (stations 2-6) will be counterbalanced across subjects.*
Part B – Follow-up testing is the same as Part B – Initial testing (see section 7C for procedures) with the following exception:

C At check-in, children who were prescribed glasses in Part A will probably already be wearing eyeglasses. Their eyeglasses should be adjusted and read on the lensmeter, and reading should be recorded on the Check-in page. Children who were not prescribed eyeglasses in Part A will be dispensed an appropriate temporary pair from the stock supply.

D. Part C - Management of Children with Below Normal Acuities and Ocular Abnormalities Other Than Refractive Error

1. Definition of Below Normal Acuity

For purposes of this study, children are defined as having below normal acuity if their visual acuity in either eye is 20/40 or worse on Session B2 testing. This implies that the children were seen, given a prescription for glasses, and the glasses were worn for a one-month period of time.

There are several reasons why a child will have decreased acuity on follow-up testing. Session C testing will determine whether the child has decreased acuity because of improper or unacceptable spectacles, or if the decreased acuity is amblyopia.

2. Decreased Acuity Related to Failure of a Hyperopic Child to Relax Accommodation Completely

At Session B2 testing, a child may complain of decreased acuity because the spectacles are “too strong for them”. These children are typically hyperopic, with a resting tonic accommodative state that is greater than the spherical cut in the hyperopic correction that is provided by our spectacle-prescribing protocol.

We anticipate that most children who are hyperopic will adapt to the glasses during the month between the B1 (dispensing) and B2 test sessions. However, there may be an occasional child who does not relax accommodation and who has decreased acuity while wearing the prescription.
Children who present at B2 sessions with significant hyperopia and who indicate that the glasses feel “too strong” will be re-examined by the eye care practitioner will re-examine the child during a C (re-check) test session. The examiner will test the child in an undilated state and perform a manifest refraction. The goal of the manifest refraction is to start at the full spherical correction in each eye and symmetrically decrease the spherical power until the child “feels comfortable”, while still maintaining 20/20 acuity in each eye. The full cylinder correction will be given in each eye, as determined by the cycloplegic autorefraction conducted during Session A1.

It will be acceptable to decrease the power of the sphere to the point where a spherical equivalent of 0 is given. This may result in an actual negative sphere prescription being given. For example, a child may have a refraction of +2.00 +3.00 x 090. If the glasses for this child feel “too strong”, the eye care practitioner, at his or her discretion, may decrease the plus spectacle correction to -1.50 +3.00 x 090, provided a symmetrical cut is provided for the two eyes.

3. **Children with Decreased Acuity and Unequal Refractive Error**

Children who have anisometropia and decreased acuity in one eye will receive spectacles as an initial treatment. If the child subsequently receives occlusion therapy or optical penalization for treatment of amblyopia, any data collected after the beginning of treatment will be excluded from analysis. Best medical judgment is used in deciding what information should be sent to parents.

4. **Children with Decreased Acuity and Equal Refractive Error**

Children who have 20/40 or worse acuity in either eye on Session B2 testing, and who have symmetrical refractive error (with a between-eye difference of 1.5 D spherical equivalent or less, which is the definition of anisometropia used in this study) will be re-examined at a C test session. If these children have no apparent strabismus or microstrabismus on careful testing, and no evidence that a change in prescription of 0.5 VDD or more is needed, their data will be included in the analysis, as the preferred treatment for these amblyopic children is spectacle wear.
5. **General Follow-up of Children with Asthenopia or Complaints of Decreased Vision**

Some children will find their glasses unacceptable, and at the request of any parent, the eye care practitioner will perform an undilated follow-up examination during a C session (which will occur after the child’s B2 session), to verify that the glasses are prescribed correctly or to match a prior pair of glasses that were acceptable to the child.

For the purposes of this study, children are defined as having amblyopia, or below normal acuity, if their visual acuity in either eye is 20/40 or worse on Session B2 testing. This implies that the children were seen, given a prescription for glasses, and the glasses were worn for a one-month period of time. In general, there are several reasons why a child on follow-up testing will have decreased acuity. The following protocol is necessary to distinguish the child who has poor decreased acuity because of improper or unacceptable spectacles from a child with decreased acuity because of amblyopia.

6. **Children with Strabismus, Medial Opacity, or Structural Anomalies of the Eye**

Children with strabismus (constant esotropia, constant exotropia, constant hypertropia, manifest nystagmus), medial opacity, or structural abnormalities of the eye (iris coloboma, cataract, lenticonus, corneal scar on visual axis, pseudophakia, optic nerve hypoplasia, retinal coloboma) are referred out of the study for continued care. While they may continue to participate in receiving spectacles, they are excluded from data analysis.
8. GUIDELINES FOR DISPENSING GLASSES AND MONITORING GLASSES WEAR

A. Parental Notification

Prior to Part B – Initial testing sessions, parents of children who were prescribed eyeglasses in Part A will be contacted by letter to notify them that their child was found to require eyeglasses. The letter explains the importance of having the child wear glasses, and encourages parents to call program staff if they have concerns or questions.

B. Filling Glasses Prescriptions

Lens power will be checked by study staff (PI or RA) before glasses are distributed to children. Lenses may vary by no more than the following amounts from the power prescribed:

- 0.25 D sphere
- 0.25 D cylinder
- 5 degrees axis for cylinder power ≤ 1.5 D
- 7 degrees axis for cylinder power < 1.5 D

Lenses that are not within these limits will be returned to the manufacturer for correction.

C. Dispensing Replacement Glasses

1. Fit/adjust frames.

2. Record dispensing date on the log sheet.

3. Return original order slip (enclosed with glasses) to the PI (EMH).

D. Site (Classroom) Visits

1. The PC will visit the classroom two times per week for the 3 to 5 week period following Part B – Initial, to check on compliance with glasses wearing, to encourage glasses wearing, and to adjust the fit of the glasses, if needed. After the Part B - follow-up testing has been completed, the PC will make monthly visits to each classroom to provide adjustment for the eyeglasses and to monitor glasses wearing.
These monthly visits will continue until the one-year follow-up examinations have been completed for children in that school. Approximately one-half of the children attend schools with year-round classes, which will permit study personnel to monitor glasses wearing in the classroom in the summer months. For the remaining children, glasses wearing in summer months will be monitored through phone calls and home visits (for families without phones). If both the original pair of glasses and the replacement pair are lost or broken, a new pair will be ordered and dispensed as soon as possible (within 2-3 weeks). Teachers and parents will be encouraged to contact the PR or PC as soon as glasses are lost or broken, so that a replacement pair can be ordered.

2. Children will be encouraged to wear their glasses both at school and at home. If the glasses are lost or broken, the teacher or study staff will provide the child with replacement glasses, and study staff will order a back-up replacement pair that will be kept by the teacher or study staff (whoever gave the child the replacement pair). (Note: we will order 2 pair of glasses for each child in the older cohort and 3 pair of glasses for each child in the younger cohort. The PC will keep one pair and give them to the child only if the original pair is lost or broken. For children in the younger cohort, a spare pair will be given to the teacher, who will give them to the child to wear at school if the original pair is lost or broken. Once one of the spare pairs are given to the child, a replacement pair will be ordered immediately, to ensure that glasses are available at follow-up testing. Providing teachers with a spare pare was not done for children in the older cohort since they change classes, and therefore it was not practical for the teacher to dispense and collect glasses at the beginning and end of each day.)

3. Before a site visit, gather the glasses tracking sheets for children who have been given glasses at that site.

4. For each child who has received glasses at that site, you should record information on their glasses tracking sheet, even if the child is absent when you visit. If a child is absent, record the date of your visit, and record that the child was not present on his/her glasses tracking sheet.

5. If the child is present, record the date of the visit, whether or not the child is wearing glasses, the condition of the glasses (use your best judgment), and how often the child is wearing the glasses (ask the teacher).
6. Adjust any glasses that need adjustment.

7. If glasses need repair or replacement:
   a. Record on the back of the child’s glasses tracking sheet the date you received the glasses.
   b. Let the teacher know you will return with new/repaired glasses.
   c. Return the glasses to the PI (EMH).
9. DATA MANAGEMENT

A. Subject Rosters and Family Contact Documentation

Children will be identified by the elementary schools as being eligible for inclusion in the project. A roster of the names of these children, with date of birth, home address, phone number, parents' names, teacher's name, and classroom will be provided prior to enrollment. Each child will be assigned a unique 8-digit alphanumeric identifier, which will serve as the subject ID for the study. This information will be entered into a computer file for use by the PC, PR and RA to document interactions with the family.

Once written informed consent is obtained from the parent/guardian of a child it will be recorded in the database that the child is eligible for testing. Prior to testing at each school, a list of children eligible for testing will be generated, including information on seizure history, medication allergies, and prior reactions to dilation.

B. Report to Elementary Schools

Following each test session, a summary of results will be generated from the data files and sent to the school nurse. This list will contain the subject name, visual acuity of each eye prior to cycloplegia, presence/absence of ocular motility abnormalities, and whether spectacles were prescribed. The PI (EMH) will replace the subject IDs with the corresponding subject names and will send the list to the School Nurse.

C. Report to IHS Optometrist

With parents' permission, following each test session an IHS encounter form will be completed for each child with the results from the eye examination (forms will be generated from study computer data files). The form will contain the subject name, visual acuity of each eye prior to cycloplegia, presence/absence of ocular abnormalities, and whether spectacles were prescribed.

Completed encounter forms will be sent to the IHS Medical Records Department or to other medical personnel specified by the parent, where the forms will be filed in each child’s medical chart. Dr. Miller is listed as an IHS Medical Provider, and therefore has authorization to add records to the children’s IHS charts.
D. **Data Flow**

Prior to each test session data sheets will be generated containing the test date and test site. These data sheets are shown in Appendix A. In addition, a list of children for whom informed consent has been obtained will be generated. The list will include information on reaction to cycloplegia, seizure history, and allergies to medications.

Each child will receive a unique encounter subject number at each visit. Based on the check-in log (Station 1), the child's subject number and the child's unique ID will be matched, so that all data from a child can be stored in the child's individual folder.

E. **Data Management**

This section describes how data are collected, verified, used in prescribing glasses for the children, used for preparing reports to the school system, the Indian Health Service, and to the parents, and finally, archived. This section does not describe the statistical methods of analysis that will address primary and secondary outcome measures, as those have previously been described in the grant application. The comprehensive data collection, management, and reporting system is called SDB2. The SDB2 is a relational database comprised of a number of data files described below.

1. **Demographics Data (DEM)**

   Our consent form has a provision that a copy of the clinically significant data be reported to the child's health care provider (the Indian Health Service), if the parent consents. Our consent form also requires that the parents receive a copy of the examination results. Finally, we are providing the school with a copy of the results. All of these forms require complete identification of the child and the parents, (i.e. name, address, date of birth, parents name). As such, it is necessary for us to maintain a current demographic file on each child, in order to establish the connection between the data collected on a child and the information necessary to make the information available to legitimate agencies. These data are managed in the DEM database.

   Demographics data on participants are provided at the beginning of the school year by the schools, in the form of paper rosters that have the child’s name, date of birth, sex, parent’s name and address,
classroom, and teacher. In order to provide anonymity for the children and prevent the identification of the child from data that is stored in the research file, it was necessary to create a unique identifier for each child to establish the relation between the demographic data on each child and the examination results. This "Subject ID" or SID is an 8 character alphanumeric field that is assigned by the database at the time of registration of the child. The ID is nominally based on the initials of the child (Last/First) and the date of birth (YYMMDD).

We originally thought that by using this method of generating a subject ID, we would be able to determine the age of the child reliably during the test session, but then realized that privacy considerations might necessitate that we exclude the use of the date of birth as a component of the identifier. We find it useful and convenient to use the present format of generating an identifier, but do not rely on the SID to indicate the age of the child, for we realize that it may be necessary to go to a more random method of key generation. Instead, at the beginning of the test session, we reference the demographics database to obtain the date of birth.

As there are instances where children have the same initials and date of birth (e.g.: twins named Jimmy and Johnny Jones), the program first prepares a first approximation of the subject ID and searches the database for a collision, indicating that the proposed SID is already in use. If a collision exists, the second letter of the proposed SID is incremented in the alpha sort sequence, (e.g. SA930101 to SB930101) and the database is again searched for a collision. The process is repeated until a unique identifier is found for the child in question.

2. Schedule Data (SKD)

We use a form of encounter tracking to connect the information about a child back to the demographic database. Whenever a child is examined for any purpose (Part A, Part B – Initial, Part B-Follow-up) a unique, sequential numeric number is assigned to that encounter. This encounter tracking is managed by the Schedule (SKD) database.

The use of the pre-assembled and pre-numbered test booklet eliminates the possibilities of the testers incorrectly copying the child’s number from the sticker, and it allows us to counterbalance test order (relevant for Part B) by manipulating the order of test pages in advance.
3. **Linked Data Files**

Data for each encounter (identified by indicated by sticker number) from each test station will be stored in separate files, and will be linked to the SKD file by the encounter number. A list of the database files are as follows:

ANT  anterior segment  
BIO  binocular indirect ophthalmoscopy (fundus)  
BYE  check-out  
CRM  cycloplegic Retinomax  
DEM  demographics  
FIT  fitting of spectacles  
GTT  drops (guttae)  
REG  registration  
CSR  cycloplegic subjective refinement and fundus exam  
SEA  screening ETDRS acuity  
SKD  schedule  
CCS  corrected contrast sensitivity  
CEA  corrected ETDRS acuity  
CGA  corrected grating acuity  
CVA  corrected vernier acuity  
SAC  stereo acuity

4. **Data Validation Procedures**

Once all data from a given test session have been entered into the screening database, a “proof sheet” is printed that is a complete summary of all the data entered. A member of the staff will then pull the paper records for that encounter and verify that the data entered in the computer match that on the handwritten logs. Any edits will be made, and once verified, the person who verified the data enters a screen in the database program that allows marking that encounter as having been verified. Each record for that encounter has a read-only field set by this process, and further edits are not possible from within the screening database (SDB2) program.

5. **Data Archiving**

At the conclusion of each data entry session a backup of the database is made on a fresh diskette. The database, in compressed
form, will fit on a single 1.44 Mbyte floppy. The low cost of floppy disks justifies the “rolling backups” that are described, rather than the more commonly implemented father/grandfather backup system used to backup systems to tape.

As the data structures change as fields are modified within the database, and as the SDB2 executable program can also change over time and not be compatible with various stages of the database files, it is also necessary to retain backups of the calling program. The archive of executable files is maintained on one hard drive and backed up on a second hard drive. The current version of the executable program, as well as the prior version of the executable program, are also maintained on floppies that are kept in the PI’s briefcase, and so if her primary development machine and LAN server should go up in smoke from a lightning strike, the current and prior versions of the SDB program exist on floppy.

6. **Authoritative Database Location**

One great concern about a database that requires access by so many individuals is that different versions of the database may evolve, as a result of one site doing an update at the same time as a second site. This could easily occur as the PI, Co-PI and Secretary administrative offices are at the Department of Ophthalmology (University of Arizona Campus), while the records are maintained and data entry is performed at the Infant Vision Laboratory (about 5 miles distant).

We chose to limit database modification to one site at a time by placing the authoritative database on a single computer located in the Infant Vision Laboratory. This machine can be connected to other desktop computers in the lab to access the database. However, unless the computer can be found on the network, data entry or revision cannot occur.

7. **Data Reporting**

The SDB2 relational database is comprised of 16 tables that are related by either Subject ID or Encounter Number. Statistical analysis is more easily achieved by a single file having the fields of interest contained within a single row of a table. The SDB2 program provides a means for defining a data extract file, indicating the fields of interest, and having all related information from that encounter joined together in a single output table. Should a missing record be
identified within the encounter (for example, for a child that left before completing all stations would not have entries in the tables for the stations that they did not attend) the fields have exclusion values entered into the fields. Exclusion values for numeric values are all 9’s. Logical fields are left empty, with neither true nor false asserted. Text fields are left blank. Up to 255 fields can be extracted at a time.

8. *Database Implementation*

The SDB2 database is implemented in the Microsoft Access Database. The extract files can be read by essentially any application, including Excel, Access, and SPSS.
10. BIBLIOGRAPHY


APPENDIX A

Letters and Forms Related to Testing of Children

C Parental Consent Form

C Letter to Parents Regarding Child Participation
C Eye Care/Medical History Form
C Parent Contact Information Form
C Letter to Parents Regarding Use of Eye Drops
C Letter to Parents of Children Receiving Glasses
C Letter to Parents of Children Not Receiving Glasses
C Letter to Parents of Children Whose Results Were Not Normal
   (Problem Other than Refractive Error)
C Thank You Letter to Teachers
I am being asked to read the following material to ensure that I am informed of the nature of this research study and of how my child will participate in it, if I consent to do so. Signing this form will indicate that I have been so informed and that I give my consent. Federal regulations require written informed consent prior to participation in this research study so that I can know the nature and risks of my child’s participation and can decide to participate or not participate in a free and informed manner.

**Purpose:** My child is being invited to participate voluntarily in the above-titled research project. The purpose of this project is to determine the effectiveness of glasses prescription on the vision of children with high astigmatism. The investigator’s goal is to determine how much vision improves when glasses are prescribed for children with astigmatism.

**Selection Criteria:** My child is being invited to participate because he/she may have high refractive error or astigmatism, indicating a need for eyeglasses. Children who have a Native American or Mexican American heritage are especially likely to have high astigmatism. Approximately 1,000 children in grades kindergarten through 6th grade will be invited to participate in this study.

**Procedure:** All examinations and testing will be conducted during school hours at my child’s school. If I agree to allow my child to participate, my child will undergo a complete eye examination that includes the use of eye drops (cyclopentolate) to dilate the pupils. After the drops have dilated my child’s pupils, he/she will be examined by the eye doctor for refractive error and astigmatism. I will be able to remain with my child at all times, and either I or my child may ask questions at any time.
Approximately 3 weeks after the eye examination, my child will have his/her vision tested. During the vision testing, my child will wear glasses, to be sure his/her best possible vision is being measured. My child will be asked to identify letters, striped patterns, and broken lines. At this time, children who require eyeglasses (based on the results of the eye examination) will be given a pair of glasses. Approximately 3-5 weeks later, my child will participate in a second vision testing session that will be identical to the first.

Approximately one year following the eye examination, my child will participate in a second eye exam session, identical to the first. Approximately 3 weeks after the second eye exam, my child will participate in another vision testing session. At this time, children who require eyeglasses (based on the results of the second eye examination) will be given a pair of glasses.

**Risks:** Testing will be conducted during school hours, so my child may miss class for about 15 minutes for each eye examination and 15 minutes for vision testing. During the eye examination, my child will receive eye drops that produce a mild stinging sensation lasting only a few seconds. The pupils will remain dilated for a few hours and then return to normal. Some children may experience a mild, transient sensitivity to light (sunglasses will be provided). If the child is farsighted and does not have glasses, his/her vision will be blurred for 1 to 2 hours. Some children become sleepy, confused, or hyperactive after they get the drops. Occasionally, a child will have flushed skin or a fast heartbeat. These conditions do not require treatment and will go away within 4 to 6 hours. Either I or my child may ask for testing to be stopped at any time. There are no known risks of the vision testing procedures.

**Benefits:** I may receive useful information about my child’s eyes. I will be helping to gain more knowledge about the best way to screen children for astigmatism and amblyopia. If my child receives a complete eye examination and the doctor determines that my child would benefit from wearing eyeglasses, my child will receive a free pair of eyeglasses.

**Participation Costs and Subject Compensation:** The eye examinations and vision testing sessions will be performed at no cost to me or my child. My child will not be paid for participation.

**Confidentiality:** All records will be coded by letters or numbers and will remain confidential. If I would like, the results of testing will be supplied to my child’s doctor. If I am a member of the Tohono O’Odham Nation, designated representatives of the Tohono O’Odham Nation Tribal Health Office will have access to test results, but not my name or my child’s name unless I wish to provide them this information. I may indicate the person(s) to whom test results should be sent at the bottom of this form.
Contacts: If I have any questions, I can obtain further information from Joseph M. Miller, M.D. at 321-3677 at the University of Arizona. If I have any questions about my rights, or those of my child, as a research subject, I may call John Kittredge, M.D., at 383-7200 at Sells Service Unit (if I am a member of the Tohono O’Odham Nation), or the University of Arizona Human Subjects Committee office at 626-6721.

Authorization: Before giving my consent by signing this form, the methods, inconveniences, risks, and benefits have been explained to me and my questions have been answered. Either I or my child may ask questions at any time and I am free to withdraw my child from the project at any time without causing bad feelings or affecting my child's medical care. My child's participation in this project may be ended by the investigator or by the sponsor for reasons that would be explained. New information developed during the course of this study which may affect my willingness to continue in this research project will be given to me as it becomes available. This consent form will be filed in an area designated by the Human Subjects Committee with access restricted to the principal investigator, Joseph M. Miller, M.D., or authorized representative of the Ophthalmology Department. I do not give up any of my legal rights, or those of my child, by signing this form. A copy of this signed consent form will be given to me.

____________________________________
Subject’s (Child’s) Name

____________________________________
Parent/Legal Guardian (if necessary)   Date

____________________________________
Witness (if necessary)   Date

For the purpose of this project, you may obtain information from my child’s medical records. Please send a report concerning the results of this test to the following medical personnel:

____________________________________
____________________________________
____________________________________

Parent’s Initials: ___________                    Witness: ____________________________

Investigator’s Affidavit: I have carefully explained to the parent or legal
guardian of the subject the nature of the above project. I hereby certify that to
the best of my knowledge the person who is signing this consent form
understands clearly the nature, demands, benefits, and risks involved in his/her
child’s participation and his/her signature is legally valid. A medical problem or
language or educational barrier has not precluded this understanding.

___________________________________ ________________________________
Signature of Investigator Date
Letter to Parents Regarding Child Participation

Dear Parent or Guardian:

The National Eye Institute has recently funded a program that will provide free eye examinations and eyeglasses to children who attend elementary school on the Tohono O’Odham reservation. The program is an extension of the Tohono O’Odham Vision Screening Program, which provided eye care to preschool children. The Tohono O’Odham Vision Screening Program has received the support of the Tohono O’Odham Legislative Council.

This spring, all of the children in the San Xavier Mission School will be eligible to receive free eye examinations as part of the program. In addition, the children who require eyeglasses will be provided with a pair of eyeglasses free of charge. Next year we will return to the school and re-examine the children to determine how much their vision has improved, to update their eyeglass prescriptions, and to provide them with a new pair of eyeglasses.

We would like to invite your child to participate in the program. If you choose to allow your child to participate, he or she will receive a complete eye examination by an optometrist or ophthalmologist during school hours on school grounds. We will be sure to contact you following your child’s eye examination to let you know the results of the examination, and to let you know if your child requires eyeglasses. If glasses are required, we will order a pair of glasses for your child, and deliver them to your child at school, free of charge.

If you would like your child to participate, please read the enclosed information, complete the enclosed forms, and return them in the stamped envelope provided. If you have any questions regarding the program, please don’t hesitate to contact us. Our program staff can be reached in Tucson at (520) 324-3162 (Erin Harvey) or in Sells at (520) 383-6207 (Frances Lopez and Irene Adams).

Sincerely,

Joseph M. Miller, M.D., M.P.H.
Associate Professor, Ophthalmology and Optical Sciences
Director, Tohono O’Odham Vision Screening Program
The Tohono O’Odham Vision Screening Program

In 1997, the Tohono O’Odham Vision Screening Program began providing eye examinations and eyeglasses for Tohono O’Odham preschool children. The results of the examinations indicated that approximately 33% of the preschool children required eyeglasses for astigmatism.

Since the program was initiated in 1997, we have provided vision screenings for many grade-school members of the Tribe. Results of the vision screenings indicated that:

- **C 46% (605/1327) of 1st-8th grade children failed the vision screening and required follow-up eye care to see if an eye problem was present.**

- **C Approximately 42% of the grade-school children require eyeglasses for astigmatism.**

- **C Few children (7%) were wearing eyeglasses.**

Clearly, many Tohono O’Odham school children would benefit from additional access to eye examinations and eyeglasses.

What can we do to assure that the children can see better?

In the second phase of the Tohono O’Odham Vision Screening Program, we will provide eye examinations and eyeglasses to Tohono O’Odham grade school children. In Spring, 2001, the Tohono O’Odham Vision Screening Program will work with children at the San Xavier Mission School.

The best way to reach as many of the children as possible is by seeing them in the schools. For the project to be effective, we will require the help and support of school superintendents, principals, teachers, and parents.

If your child attends San Xavier Mission School, we would like to invite him or her to participate in the program!

If you would like your child to participate, please complete the enclosed forms, and return them in the stamped envelope provided.
Eye Care/Medical History

Child’s Name: __________________________  Child’s Date of Birth _____________

1. Has your child ever been given eye drops to dilate his/her eyes?
   No   Yes
   If yes, did your child have a bad reaction to the eye drops?
   No   Yes
   If yes, please explain briefly ________________________________

2. Does your child have any special needs?
   No   Yes
   If yes, please explain briefly ________________________________

3. Does your child currently wear eyeglasses?
   No   Yes

4. Has your child ever had eyeglasses?
   No   Yes

5. Has your child ever had a serious eye injury?
   No   Yes
   If yes, please explain briefly ________________________________

6. Has your child ever had strabismus (a “lazy eye” that turns in or turns out)?
   No   Yes
   If yes, did your child have any of the following treatments?
   Eyeglasses   Patching   Surgery   Other

7. Has your child ever had any other eye problem that was treated by a doctor?
   No   Yes
   If yes, please explain briefly ________________________________
10. Was your child seen by the eye doctor in Head Start, as part of the Tohono O’Odham Vision Screening Program?
   No  Yes

11. Has your child ever had an eye examination, or been seen by an eye doctor?
   No  Yes

12. Please record as much information as you can about each of your child’s previous eye examinations, starting with the most recent exam.

    (a) Clinic __________________________________________________________
        Doctor _________________________________________________________
        Date _________  Child’s Age _________  Child’s Grade _________

        What was the reason for the exam?
        Routine check-up  New glasses  Eye Injury  Vision Trouble

        Did the doctor prescribe or recommend glasses for your child? Yes  No

        If yes, did your child get eyeglasses after this exam? Yes  No

        If yes, did your child wear the glasses?
        Never  Rarely  Sometimes  Often  Always

        How long did your child have the glasses?
        < 1 Month  2-6 Months  1 Year  >1 Year  Still Has Them
<table>
<thead>
<tr>
<th>Clinic</th>
<th>________________________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor</td>
<td>________________________________</td>
</tr>
<tr>
<td>Date</td>
<td>Child’s Age</td>
</tr>
</tbody>
</table>

**What was the reason for the exam?**
- Routine check-up
- New glasses
- Eye Injury
- Vision Trouble

**Did the doctor prescribe or recommend glasses for your child?** Yes  No

**If yes, did your child get eyeglasses after this exam?** Yes  No

**If yes, did your child wear the glasses?**
- Never
- Rarely
- Sometimes
- Often
- Always

**How long did your child have the glasses?**
- < 1 Month
- 2-6 Months
- 1 Year
- >1 Year
- Still Has Them

---

<table>
<thead>
<tr>
<th>Clinic</th>
<th>________________________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor</td>
<td>________________________________</td>
</tr>
<tr>
<td>Date</td>
<td>Child’s Age</td>
</tr>
</tbody>
</table>

**What was the reason for the exam?**
- Routine check-up
- New glasses
- Eye Injury
- Vision Trouble

**Did the doctor prescribe or recommend glasses for your child?** Yes  No

**If yes, did your child get eyeglasses after this exam?** Yes  No

**If yes, did your child wear the glasses?**
- Never
- Rarely
- Sometimes
- Often
- Always

**How long did your child have the glasses?**
- < 1 Month
- 2-6 Months
- 1 Year
- >1 Year
- Still Has Them

---

A.9
(d) Clinic ________________________________

Doctor ________________________________

Date ___________  Child’s Age ___________  Child’s Grade ________

What was the reason for the exam?
  Routine check-up  New glasses  Eye Injury  Vision Trouble

Did the doctor prescribe or recommend glasses for your child? Yes  No

If yes, did your child get eyeglasses after this exam?  Yes  No

If yes, did your child wear the glasses?
  Never  Rarely  Sometimes  Often  Always

How long did your child have the glasses?
  < 1 Month  2-6 Months  1 Year  >1 Year  Still Has Them
Parent Contact Information Form

The following information is needed so that we can provide an eye exam for your child, and contact you with the results of the examination. Please take a moment to fill out this form. If you have any questions, please let us know. Thank You!

Child’s Name:_________________________________________________
Child’s Date of Birth:___________________________________________
Child’s School: __________________________  Child’s Grade: _________
Parent’s Name:________________________________________________
Parent’s Phone #:______________________________________________
Message Phone #:_____________________________________________
Parent’s Mailing Address:________________________________________

Child’s Primary Care Physician (please circle one):

Sells IHS      San Xavier IHS      Santa Rosa IHS

IHS Chart #: ______________________

Other Physician (name & address):________________________________

_________________________________________________
Letter to Parents Regarding Use of Eye Drops

Dear Parent:

Thank you for allowing your child to participate in our eye examination program today. Part of this examination required the use of eye drops. These eye drops may make your child sensitive to light and have blurred vision. This side effect should wear off by the end of the day tomorrow.

There are some side effects to the eye drops you should watch out for. The medicine in the eye drops most often makes children sleepy, but some children may become hyperactive or confused. This will wear off quickly. Occasionally, more serious side effects, such as flushed skin or a fast-beating heart can occur. If this should happen after your child is home, please contact me immediately by calling me at 694-6000, beeper 1269, and I will call you back to discuss the problem and, if necessary, I will arrange for your child to be seen. If you cannot reach me, call 911.

We will send you a letter within the next week regarding your child’s eye exam results. Again, thanks for the opportunity to examine your child. I hope it has been beneficial.

Sincerely,

Joseph M. Miller, M.D., M.P.H.
Associate Professor, Ophthalmology and Optical Sciences
Director, Tohono O’Odham Vision Screening Program
Letter to Parents of Children Receiving Glasses

Dear Parent:

Your child had an extensive eye examination today and was found to require eye glasses. These glasses will be provided to your child within the next few weeks at no cost to you. It is important for you to encourage your child to wear these glasses, because we found that your child does not see well without the glasses. If your child does not see well and glasses are not worn, amblyopia (or lazy eye) can develop. It appears that many children of the Tribe do have amblyopia, and so we are trying to prevent and treat this problem in the children while they are still young and it is easier to treat.

Most children who need glasses do not fight about wearing them after a couple weeks of encouragement. Sometimes they do say that the glasses make them feel sick or that they do not feel right. If after two weeks of trying to encourage your child to wear the glasses and your child still will not wear them, please contact our office at (520) 383-6207 (Sells) or at (520) 324-3162 (Tucson). Perhaps, the prescription is wrong or the glasses do not fit correctly. Either way, your child would not want to wear them, and we need to fix them because we are certain that your child does need glasses.

Glasses need to be worn at all times for them to work at preventing and treating amblyopia. It does not work well for a child to be allowed to wear the glasses for part of the day and take them off for part of the day, because the glasses are needed at all times. Also, when they are taken off and put on, they are frequently either lost or scratched. Wearing the glasses at all times prevents this problem. I tell children that they should only take the glasses off in the bathtub or in bed.

If your child’s glasses become lost, badly scratched, or broken, please let your child’s teacher know, and he or she will contact us to get the glasses replaced, or you can contact our program staff directly at (520) 383-6207 (Sells) or at (520) 324-3162 (Tucson).

Please feel free to contact me at (520) 321-3677 if you have any questions about the glasses or their use.

Sincerely,

Joseph M. Miller, M.D., M.P.H.
Associate Professor, Ophthalmology and Optical Sciences
Director, Tohono O’Odham Vision Screening Program
Letter to Parents of Children Not Receiving Glasses

Dear Parents:

Your child received an eye examination as part of the Tohono O’Odham Vision Screening Program. After review of your child's results, we have determined that your child has normal vision and does not require glasses at this time.

If you have any further questions regarding your child's results, please contact our program staff at (520) 383-6207 (Sells) or at (520) 324-3162 (Tucson).

Thank you for the opportunity to see your child.

Sincerely,

Joseph M. Miller, M.D., M.P.H.
Associate Professor, Ophthalmology and Optical Sciences
Director, Tohono O’Odham Vision Screening Program
Letter to Parents of Children Whose Results Were Not Normal (Problem Other Than Refractive Error)

Dear Parents,

Your child received an eye examination as part of the Tohono O’Odham Vision Screening Program. The results of testing indicate that your child has an eye problem that requires careful follow-up eye examinations.

When you gave permission for your child to participate in this program, you also indicated that we should send a copy of our findings to your child’s doctor. Our records indicate that your child’s doctor is doctor’s name and address. [If the address is unknown, we will write: We have no records of your child’s doctor. Please contact our program staff at (520) 383-6207 (Sells) or at (520) 324-3162 (Tucson) as soon as possible to let us know the name of your child’s doctor.]

If you have any questions, please contact our program staff at (520) 383-6207 (Sells) or at (520) 324-3162 (Tucson).

It was a pleasure to examine your child. I hope that through the efforts of the Tohono O’Odham Vision Screening Program, your child will enjoy a lifetime of good vision.

Thank you for your help in ensuring this.

Best personal regards,

Joseph M. Miller, M.D., M.P.H.
Associate Professor, Ophthalmology and Optical Sciences
Director, Tohono O’Odham Vision Screening Program

cc: Indian Health Service
**Thank You Letter to Teachers**

Dear _______________

Thank you for your support and assistance in our recent visit to perform a comprehensive eye examination on the children in your classroom.

If there were children who were absent for testing, we would like to arrange for them to attend a future test session. We will contact you to verify the names of these children, and to set up a future test date. As we discussed in our original meeting, we have a goal of 100% participation in this project, along the same lines as the vaccination program. We appreciate your help in this matter. We could not do it without you!

We will be in touch with you shortly with the glasses for those children who require them. We will also send you a postcard periodically to ask if, in fact, the children are continuing to wear the glasses. I would appreciate it if you would mark that postcard and drop it in the mail shortly after it arrives. If we see that a child is not wearing their glasses, we will contact you to try and figure out why they are not.

Again, our sincere thanks for a most successful day of vision screening.

Best personal regards,

Joseph M. Miller, M.D., M.P.H.
Associate Professor, Ophthalmology and Optical Sciences
Director, Tohono O’Odham Vision Screening Program
APPENDIX B

Data Sheets
### STANDARD ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANT</td>
<td>anterior segment</td>
</tr>
<tr>
<td>BIO</td>
<td>binocular indirect ophthalmoscopy (fundus)</td>
</tr>
<tr>
<td>BYE</td>
<td>check-out</td>
</tr>
<tr>
<td>CRM</td>
<td>cycloplegic Retinomax</td>
</tr>
<tr>
<td>DEM</td>
<td>demographics</td>
</tr>
<tr>
<td>FIT</td>
<td>fitting of spectacles</td>
</tr>
<tr>
<td>GTT</td>
<td>drops (guttae)</td>
</tr>
<tr>
<td>REG</td>
<td>registration</td>
</tr>
<tr>
<td>CSR</td>
<td>cycloplegic subjective refinement and fundus exam</td>
</tr>
<tr>
<td>SEA</td>
<td>screening ETDRS acuity</td>
</tr>
<tr>
<td>SKD</td>
<td>schedule</td>
</tr>
<tr>
<td>CCS</td>
<td>corrected contrast sensitivity</td>
</tr>
<tr>
<td>CEA</td>
<td>corrected ETDRS acuity</td>
</tr>
<tr>
<td>CGA</td>
<td>corrected grating acuity</td>
</tr>
<tr>
<td>CVA</td>
<td>corrected vernier acuity</td>
</tr>
<tr>
<td>SAC</td>
<td>stereo acuity</td>
</tr>
</tbody>
</table>
Stations 1A and 8A

REGISTRATION and CHECK-OUT
(REG)                        (BYE)

Test Date____________________

Test Location_________________

Tester_______________________

Sticker#______________________

Nickname_____________________

<table>
<thead>
<tr>
<th>Gender</th>
<th>F</th>
<th>M</th>
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<tbody>
<tr>
<td>Sticker Number</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check-In Time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glasses (Read Lenses)</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Contacts</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Prior Reaction to Dilation (If Yes, mark No Drops on Station 5A.)</td>
<td>Y</td>
<td>N</td>
</tr>
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</table>

<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Tape Lensmeter Printout Here</td>
<td></td>
</tr>
</tbody>
</table>

Check-Out Time

Letter(s) Given to Child or Teacher? | Y | N |

Comments
### UNDILATED ETDRS ACUITY (UEA)

#### Correction Worn During Testing?

<table>
<thead>
<tr>
<th>Glasses</th>
<th>Contacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>N</td>
</tr>
</tbody>
</table>

/ = wrong

\( \Diamond \) = corrected (not wrong)

<table>
<thead>
<tr>
<th>First Name</th>
<th>Sticker #</th>
</tr>
</thead>
</table>

#### Test Details

- **Test Date**: __________
- **Test Location**: __________
- **Tester**: __________

#### Chart 1 (Right Eye)

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Acuity</th>
</tr>
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<tbody>
<tr>
<td>O</td>
<td>20/20</td>
</tr>
<tr>
<td>H</td>
<td>20/16</td>
</tr>
<tr>
<td>Z</td>
<td>20/12</td>
</tr>
<tr>
<td>V</td>
<td>20/10</td>
</tr>
<tr>
<td>K</td>
<td>20/08</td>
</tr>
<tr>
<td>Z</td>
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<td>H</td>
<td>20/02</td>
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<td>20/00</td>
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<tr>
<td>K</td>
<td>20/08</td>
</tr>
<tr>
<td>O</td>
<td>20/10</td>
</tr>
</tbody>
</table>

**Last Line with 3 Correct**: __________

#### Chart 2 (Left Eye)

<table>
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<tr>
<th>Symbol</th>
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<tbody>
<tr>
<td>Z</td>
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<tr>
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</tr>
<tr>
<td>O</td>
<td>20/04</td>
</tr>
<tr>
<td>S</td>
<td>20/02</td>
</tr>
<tr>
<td>D</td>
<td>20/01</td>
</tr>
<tr>
<td>V</td>
<td>20/00</td>
</tr>
<tr>
<td>K</td>
<td>20/08</td>
</tr>
<tr>
<td>O</td>
<td>20/10</td>
</tr>
</tbody>
</table>

**Last Line with 3 Correct**: __________

#### Comments

- **# Letters**
- **Confidence**

| 5 - Very sure I got the correct acuity score |
| 4 - High confidence - pretty sure acuity is correct but not absolutely sure |
| 3 - Only moderate confidence that acuity score is correct |
| 2 - Very unsure about acuity result |
| 1 - No confidence in this result |

---

B.3
Station 3A

STEREO ACUITY (SAC)

<table>
<thead>
<tr>
<th>Correction Worn During Testing?</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Glasses</td>
<td>Contacts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
</tbody>
</table>

○ = correct
/ = wrong
○/ = corrected (not wrong)

PRETEST
Book 3

<table>
<thead>
<tr>
<th>Correct</th>
<th>Incorrect/Unable</th>
</tr>
</thead>
</table>

BOOK 3

<table>
<thead>
<tr>
<th>top 800&quot;</th>
<th>heart</th>
<th>duck</th>
<th>square</th>
</tr>
</thead>
<tbody>
<tr>
<td>bottom 400&quot;</td>
<td>tree</td>
<td>star</td>
<td>circle</td>
</tr>
</tbody>
</table>

BOOK 1

<table>
<thead>
<tr>
<th>top 200&quot;</th>
<th>truck</th>
<th>hand</th>
<th>heart</th>
</tr>
</thead>
<tbody>
<tr>
<td>bottom 100&quot;</td>
<td>star</td>
<td>house</td>
<td>car</td>
</tr>
</tbody>
</table>

BOOK 2

<table>
<thead>
<tr>
<th>top 60&quot;</th>
<th>elephant</th>
<th>hand</th>
<th>circle</th>
</tr>
</thead>
<tbody>
<tr>
<td>bottom 40&quot;</td>
<td>tree</td>
<td>house</td>
<td>duck</td>
</tr>
</tbody>
</table>

Circle last disparity level with at least 2 of 3 forms correctly identified

Confidence

Confidence Ratings
5 - Very sure I got the correct acuity score
4 - High confidence - pretty sure acuity is correct but not absolutely sure
3 - Only moderate confidence that acuity score is correct
2 - Very unsure about acuity result
1 - No confidence in this result

Unable To Do Test
□ Wouldn’t wear glasses
□ Wouldn’t identify shape

No Stereopsis
□ Couldn’t find stereo figure
Station 4A

Test Date__________________________

PUPILS, ANTERIOR SEGMENT, AND MOTILITY (ANT)

Test Location__________________________

Tester__________________________

Sticker #__________________________

First Name__________________________

<table>
<thead>
<tr>
<th>Pupils</th>
<th>Anterior Segment</th>
<th>Motility</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RE</td>
<td>LE</td>
</tr>
<tr>
<td></td>
<td>Pass</td>
<td>Fail</td>
</tr>
</tbody>
</table>

Comments

B.5
AC:DAT Manual of Procedures

Station 5A

Test Date_____________________

CYCLOPLEGIC DROPS (GTT)

Test Location__________________

Tester________________________

Sticker #_______________________

First Name_____________________

<table>
<thead>
<tr>
<th>Contraindications</th>
<th>First Drop (Proparacaine) and Second Drop (1% Cyclogyl)</th>
<th>Third Drop (1% Cyclogyl)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Time</td>
<td>Time</td>
</tr>
<tr>
<td>Previous Reaction to Dilation</td>
<td><em>Y</em></td>
<td>N</td>
</tr>
</tbody>
</table>

*Y* If yes, NO drops given!

Comments
AAC:DAT Manual of Procedures

Station 6A

CYCLOPLEGIC RETINOMAX (CRM)

Test Date____________________

Test Location__________________

Tester________________________

Sticker #_____________________  

First Name____________________  

Printout #1

Printout #2
**Station 7A**

**CYCLOPLEGIC SUBJECTIVE REFINEMENT AND FUNDUS EXAM (CSR)**

**Test Date**

**Test Location**

**Tester**

**Sticker #**

**First Name**

**Step 1:** Copy cylinder and axis from Retinomax 1, and verify that cylinder and axis are within 4 clicks.

<table>
<thead>
<tr>
<th>Cycloplegic Retinomax 1 (CRM1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sphere</td>
</tr>
<tr>
<td>RE 1</td>
</tr>
<tr>
<td>LE 1</td>
</tr>
</tbody>
</table>

**Step 2:** If cylinder and axis are not within 4 clicks, obtain a second Retinomax and copy below.

<table>
<thead>
<tr>
<th>Cycloplegic Retinomax 2 (CRM2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sphere</td>
</tr>
<tr>
<td>RE 2</td>
</tr>
<tr>
<td>LE 2</td>
</tr>
</tbody>
</table>

**Step 3:** Determine sphere for RE and LE. Check block indicating whether cylinder value from CRM1 or CRM2 is used. If neither CRM1 or CRM2 are acceptable, refine and record cylinder and axis below. If child is too young for refinement, do 2 retinoscopies, recording into CSR1 and CSR2, and then use AANAC protocol for fit.

**Cycloplegic Subjective Refinement 1 (CSR1)**

<table>
<thead>
<tr>
<th>Sphere</th>
<th>Cylinder</th>
<th>Axis</th>
<th>Confidence</th>
<th>Written C.A (0)</th>
<th>CRM1 C. A (1)</th>
<th>CRM2 C. A (2)</th>
<th>AANAC (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Cycloplegic Subjective Refinement 2 (CSR2)**

(For Use with AANAC Protocol)

<table>
<thead>
<tr>
<th>Sphere</th>
<th>Cylinder</th>
<th>Axis</th>
<th>Confidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>RE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LE</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Fundus Examination**

<table>
<thead>
<tr>
<th>Pass</th>
<th>Fail</th>
</tr>
</thead>
</table>

**Confidence Ratings**

1. 5 - Very sure I got the correct acuity score
2. 4 - High confidence - pretty sure acuity is corrected but not absolutely sure
3. 3 - Only moderate confidence that acuity score is correct
4. 2 - Very unsure about acuity result
5. 1 - No confidence in this result
Stations 1B and 7B

REGISTRATION and CHECK-OUT
(REG)                       (BYE)

Test Date__________________________

Test Location_______________________

Tester______________________________

Sticker#____________________________

Nickname____________________________

<table>
<thead>
<tr>
<th>Gender</th>
<th>F</th>
<th>M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sticker Number</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check-In Time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glasses (Read Lenses)</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Contacts</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Stock Glasses (If worn, enter Stock # here)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Glasses</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Tape Lensmeter Printout Here</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Check-Out Time</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Letter Given</td>
<td>Y</td>
</tr>
<tr>
<td>Stock Glasses Returned?</td>
<td>Y</td>
</tr>
</tbody>
</table>

Comments
Station 2B

**CORRECTED ETDRS ACUITY (CEA)**

<table>
<thead>
<tr>
<th>Correction Worn During Testing?</th>
<th>Glasses</th>
<th>Contacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>/ = wrong</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>ψ = corrected (not wrong)</td>
<td>Y</td>
<td>N</td>
</tr>
</tbody>
</table>

Test Date____________________

Test Location_________________

Tester_______________________

Sticker #_________________

First Name__________________

**Chart 1 (Right Eye)**

<table>
<thead>
<tr>
<th>Chart 1 (Right Eye)</th>
<th>Last Line with 3 Correct</th>
</tr>
</thead>
<tbody>
<tr>
<td>C O H Z V</td>
<td>20/20</td>
</tr>
<tr>
<td>S Z N D C</td>
<td>20/16</td>
</tr>
<tr>
<td>V K C N R</td>
<td>20/12</td>
</tr>
<tr>
<td>K C R H N</td>
<td>20/10</td>
</tr>
<tr>
<td>Z K D V C</td>
<td>20/80</td>
</tr>
<tr>
<td>H V O R K</td>
<td>20/63</td>
</tr>
<tr>
<td>R H S O N</td>
<td>20/50</td>
</tr>
<tr>
<td>K S V R H</td>
<td>20/40</td>
</tr>
<tr>
<td>H N K C D</td>
<td>20/32</td>
</tr>
<tr>
<td>N D V K O</td>
<td>20/25</td>
</tr>
<tr>
<td>D H O S Z</td>
<td>20/20</td>
</tr>
<tr>
<td>V R N D O</td>
<td>20/16</td>
</tr>
<tr>
<td>C Z H K S</td>
<td>20/12</td>
</tr>
<tr>
<td>O R Z S K</td>
<td>20/10</td>
</tr>
</tbody>
</table>

**Chart 2 (Left Eye)**

<table>
<thead>
<tr>
<th>Chart 2 (Left Eye)</th>
<th>Last Line with 3 Correct</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z R K D C</td>
<td>20/20</td>
</tr>
<tr>
<td>D N C H V</td>
<td>20/16</td>
</tr>
<tr>
<td>C D H N R</td>
<td>20/12</td>
</tr>
<tr>
<td>R V Z O S</td>
<td>20/10</td>
</tr>
<tr>
<td>O S D V Z</td>
<td>20/80</td>
</tr>
<tr>
<td>N O Z C D</td>
<td>20/63</td>
</tr>
<tr>
<td>R D N S K</td>
<td>20/50</td>
</tr>
<tr>
<td>O K S V Z</td>
<td>20/40</td>
</tr>
<tr>
<td>K S N H O</td>
<td>20/32</td>
</tr>
<tr>
<td>H O V S N</td>
<td>20/25</td>
</tr>
<tr>
<td>V C S Z H</td>
<td>20/20</td>
</tr>
<tr>
<td>C Z D R V</td>
<td>20/16</td>
</tr>
<tr>
<td>S H R Z C</td>
<td>20/12</td>
</tr>
<tr>
<td>D N O K R</td>
<td>20/10</td>
</tr>
</tbody>
</table>

**# Letters** | **Confidence**
---|---

**Comments**

**Confidence Ratings**

5 - Very sure I got the correct acuity score
4 - High confidence - pretty sure acuity is correct but not absolutely sure
3 - Only moderate confidence that acuity score is correct
2 - Very unsure about acuity result
1 - No confidence in this result
**STEREO ACUITY (SAC)**

<table>
<thead>
<tr>
<th>Correction Worn During Testing?</th>
<th>Glasses</th>
<th>Contacts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td></td>
<td>Y</td>
<td>N</td>
</tr>
</tbody>
</table>

〇 = correct
／ = wrong
〇／ = corrected (not wrong)

### PRETEST

<table>
<thead>
<tr>
<th>Book 3</th>
<th>Correct</th>
<th>Incorrect/Unable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### BOOK 3

<table>
<thead>
<tr>
<th>top 800&quot;</th>
<th>heart</th>
<th>duck</th>
<th>square</th>
</tr>
</thead>
<tbody>
<tr>
<td>bottom 400&quot;</td>
<td>tree</td>
<td>star</td>
<td>circle</td>
</tr>
</tbody>
</table>

### BOOK 1

<table>
<thead>
<tr>
<th>top 200&quot;</th>
<th>truck</th>
<th>hand</th>
<th>heart</th>
</tr>
</thead>
<tbody>
<tr>
<td>bottom 100&quot;</td>
<td>star</td>
<td>house</td>
<td>car</td>
</tr>
</tbody>
</table>

### BOOK 2

<table>
<thead>
<tr>
<th>top 60&quot;</th>
<th>elephant</th>
<th>hand</th>
<th>circle</th>
</tr>
</thead>
<tbody>
<tr>
<td>bottom 40&quot;</td>
<td>tree</td>
<td>house</td>
<td>duck</td>
</tr>
</tbody>
</table>

- **Confidence**

  **Confidence Ratings**
  - 5 - Very sure I got the correct acuity score
  - 4 - High confidence - pretty sure acuity is correct but not absolutely sure
  - 3 - Only moderate confidence that acuity score is correct
  - 2 - Very unsure about acuity result
  - 1 - No confidence in this result

- **Unable To Do Test**
  - ☐ Wouldn’t wear glasses
  - ☐ Wouldn’t identify shape

- **No Stereopsis**
  - ☐ Couldn’t find stereo figure

---

Test Date_____________________

Test Location_________________

Tester_______________________

Sticker #_____________________

First Name___________________
Station 4B

**CORRECTED GRATING ACUITY**
*(CGA)*

Test Date________________________

Test Location______________________

Tester____________________________

Sticker #__________________________

First Name________________________

<table>
<thead>
<tr>
<th>Acuity</th>
<th>Horizontal</th>
<th>Vertical</th>
<th>Oblique</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unable to Test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unable to See Widest Stripes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.86 CPD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>26</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>38</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Confidence**

- Very sure I got the correct acuity score (5)
- High confidence, pretty sure acuity is correct but not absolutely sure (4)
- Only moderate confidence that acuity score is correct (3)
- Very unsure about acuity result (2)
- No confidence in this result (1)

**Comments**
Station 5B

**CORRECTED VERNIER ACUITY (CVA)**

<table>
<thead>
<tr>
<th>Vernier Acuity</th>
<th>Horizontal</th>
<th>Vertical</th>
<th>Oblique</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unable to Test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unable to See Largest Offset</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16 dots</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Confidence**

<table>
<thead>
<tr>
<th>Confidence</th>
<th>Horizontal</th>
<th>Vertical</th>
<th>Oblique</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very sure I got the correct acuity score</td>
<td>(5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High confidence, pretty sure acuity is correct but not absolutely sure</td>
<td>(4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Only moderate confidence that acuity score is correct</td>
<td>(3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very unsure about acuity result</td>
<td>(2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No confidence in this result</td>
<td>(1)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Comments**
<table>
<thead>
<tr>
<th>Contrast Threshold</th>
<th>1.5 cy/deg</th>
<th>6 cy/deg</th>
<th>18 cy/deg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H</td>
<td>V</td>
<td>H</td>
</tr>
<tr>
<td>Unable to Test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unable to See Highest Contrast</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
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<td></td>
<td></td>
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<tr>
<td>6</td>
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<td>7</td>
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<td></td>
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<tr>
<td>8</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

Confidence

<table>
<thead>
<tr>
<th>Confidence</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very sure I got the correct acuity score</td>
<td>(5)</td>
</tr>
<tr>
<td>High confidence, pretty sure acuity is correct but not absolutely sure</td>
<td>(4)</td>
</tr>
<tr>
<td>Only moderate confidence that acuity score is correct</td>
<td>(3)</td>
</tr>
<tr>
<td>Very unsure about acuity result</td>
<td>(2)</td>
</tr>
<tr>
<td>No confidence in this result</td>
<td>(1)</td>
</tr>
</tbody>
</table>