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Chapter 6: Enrollment and Study Visits

6.1 Procedures for Informed Consent for Enrollment

Written consent for enrollment must be obtained from each subject’s parent/guardian prior to randomization into the study. Assent for enrollment must also be obtained from each subject.

The study will be carefully discussed with the subject/guardian and informed consent (and child assent) and HIPAA authorization will be obtained in person by the principal investigator, site coordinator, or other study personnel (Appendix 2). The subject and his parent/guardian will be given the opportunity to have any questions answered. The subject and his parent/guardian can either enroll in the study at that time or take the consent/assent forms home for consideration. Consent/assent will be documented when the subject, his parent/guardian, and the study investigator sign the forms. The subject and his parent/guardian will receive a copy of the signed informed consent and assent forms. Subjects, who accept the terms of participation, sign the assent form, and whose parent/guardian sign the informed consent form will be enrolled in the study.

Enrolled subjects will be randomly assigned to one of four treatments: Home-based Pencil Push-up therapy, Home-based Pencil Push-ups with Computer VT/Orthoptics therapy, Office-based VT/Orthoptics, or Office-based Placebo VT/Orthoptics. Randomization can occur on the same day as the Eligibility Examination provided that all eligibility criteria are met. Some subjects/families may require additional time to consider enrolling in the study.

All of the subject education and informed consent activities require the participation of the clinic site’s Principal Investigator or Site Coordinator. The time required for these activities should not be underestimated. The following procedures must be followed prior to enrollment/randomization into the CITT:

6.1.1 Consent Procedure for Enrollment into the Randomized Trial

1. If the subject is eligible and interested in enrolling into the CITT study, the informed consent for randomization will be used.
2. A copy of the informed consent document will be provided and each aspect of the document will be explained.
3. It will be emphasized that participation is voluntary and that the subject can decline to participate without it adversely affecting his/her future vision care. It will also be explained that the subject can withdraw from the study at any time.
4. The various treatments for convergence insufficiency will be explained. Investigators will emphasize that the best treatment for convergence insufficiency is unknown. Some doctors recommend pencil push-up treatment, others recommend vision therapy (home- or office-based), and others do not feel any treatment is appropriate or necessary.
5. The subject and parent/guardian will be told that the purpose of the CITT is to determine if one or more of these treatments is effective and if one is more effective than the others.
6. Randomization will be explained and investigators will insure that subjects and parents/guardians understand that neither the subject nor doctor will have a choice
regarding which treatment the subject is assigned and that it is similar to flipping a coin. Each subject and parent/guardian must be willing to accept and comply with whatever treatment is the assigned treatment.

7. The subject and his/her parent/guardian will be informed that they will not know to which group the subject was assigned until all active subjects have completed the 12 month follow up appointment. At that time they will be notified either in a face-to-face meeting or by phone.

8. Subjects, parents/guardians will be informed that there is a 25 percent chance that they will be randomized into the control (Office-based Placebo VT/Orthoptics) treatment group.

9. Benefits and risks of participation will be explained.

10. The number and length of visits required will be explained.

11. The duration of the study and the importance of commitment to long-term follow-up will be discussed.

12. The amount of home therapy to be done will be explained.

13. The subject’s availability to complete the study visits will be confirmed.

14. The travel reimbursements will be discussed. It will be stressed that reimbursement is not tied to compliance.

15. An opportunity to ask questions will be provided.

16. Time will be provided to read the informed consent and assent documents.

17. Additional opportunity to ask questions will be provided.

18. All the subject’s questions must be answered. If an answer is not known, the clinician should admit frankly that it is not known and follow-up should be promised. The clinic site calls Dr. Scheiman, CITT Study Chair at 215-276-6057, to obtain the answer and then responds to the subject.

19. The subject should not be subjected to any pressure. If he/she would like to consider the study and return at a later time, that is quite acceptable.

20. The fact that the CITT is a large, national, multi-center program is emphasized. No analytical results will be available for months to years. Each subject should be reminded of the importance of his/her individual efforts.

21. A copy of the informed consent and assent forms are provided to the subject and parent/guardian. The original forms are maintained in the subject’s file in a secure area at the participating clinic.

6.1.2 Special Consent Procedures for Minors (Assent)

Because the inclusion criterion for age includes minors ages 9 to <18 years, special procedures are outlined for potentially eligible subjects who are minors. Prior to randomization, signed informed consent must be obtained from the minors’ legally authorized guardian. In addition, the minor must provide signed assent. The assent form will be written at an appropriate reading level. It should be explained that the treatment visits, home therapy, and follow-up masked examinations are within the realm of ordinary eye care. Similarly, the duration of treatment is consistent with clinical practice. Great care must be taken to explain the testing and treatment procedures to both minors eligible for the study and their parent(s)/guardian(s). Randomization and the possibility of assignment to the placebo treatment group must be explained in detail.
Each CITT clinic site will meet its Institutional Review Board’s requirements on informed consent procedures for minors. A sample assent form can be found in the appendix of this chapter.

6.2 Participation Incentives

6.2.1 Vision Correction

The CITT will only pay for eyeglasses when a patient has been wearing bifocals or prism. In these cases, to be eligible, the subject must agree to wear new glasses without the bifocal or prism.

6.2.2 Treatment for Convergence Insufficiency

Convergence insufficiency subjects enrolled in the CITT are not charged for CITT study-related examination and treatment. If a procedure is part of the CITT protocol (i.e., contained on the CITT examination forms), it is part of the CITT study-related care at that visit. If the procedure is not on the CITT examination form or if it is a non-CITT study visit, it constitutes non-study related care. Any examination procedures related to an adverse event will be considered a CITT study visit. Any equipment necessary for home vision therapy is provided free of charge to the subject. Subjects who do not have symptomatic relief at the end of the 12 week treatment phase will be referred to a doctor who is not a CITT investigator and will receive at no cost 12 weeks of an alternative treatment selected by the subject/guardian and their doctor. This alternative treatment must be initiated within one month of completion of the 12 week masked examination.

6.2.3 Compensation for Time/Travel

Enrolled subjects will receive a flat fee to partially compensate for their time and travel expenses. The compensation will be $20 for 1) the eligibility examination, 2) each completed treatment visit/phone appointment, and 3) the first 2 masked examinations (which occur after 4 and 8 weeks of treatment are completed). The subject will receive $50 for the primary outcome masked examination (after 12 weeks of treatment are completed) and the follow-up visits at 6 and 12-months. We decided on a larger payment for these three visits because they are not part of routine eye care for this condition.

Monetary payments will be distributed in spaced increments with $20 delivered after the eligibility testing, a maximum of $100 can be obtained after the 4-week masked examination (initial training + 3 weeks of training + week 4 masked exam), A maximum of $80 after the 8-week masked examination (3 weeks of training + week 8 masked exam), and a maximum of $110.00 after the 12-week masked examination (3 weeks + 12-week primary outcome examination). An additional $50.00 is obtained after the completion of the 6-month follow-up examination and $50.00 after completion of the 12-month follow-up visit.
6.2.4 Subject Incentives

All subjects will be given an incentive item such as a gift certificate for video rental, CITT T-shirt, ball cap, or novelty toy after each treatment visit. Excellent compliance for treatment and masked examination visits will be rewarded with a more significant gift item. For example, a perfect visit record with no missed appointments and all appointments within windows will receive the highest value gift item. All incentive items are meant to encourage compliance with the assigned treatment. Individual clinic sites will control the types of items and the distribution schedule.

6.3 Treatment Visits and Masked Examinations

Each subject who enrolls in the CITT will be scheduled for an initial therapy session with a Vision Therapist who will perform any associated in-office therapy procedures (for the Office-based groups only) and instruct subjects on the home therapy associated with his/her assigned treatment arm (for all four treatment groups). All subjects in each of the four treatment groups will have weekly contact with the Vision Therapist (twelve in-office visits for the two office-based groups and nine telephone appointments plus three in-office sessions for the two home-based groups). Treatment compliance will be assessed at these weekly contacts.

6.3.1 Scheduling

One treatment period extends over a one-week period. For subjects assigned to Home-based Pencil Push-up therapy or Home-based Pencil Push-ups with Computer VT/Orthoptics, this corresponds to one week of home-based therapy. A phone appointment with the Vision Therapist is scheduled at the end of each week. Similarly, for subjects assigned to either of the two office-based groups, the treatment period corresponds to one in-office training session and the following week’s associated home therapy. Ideally each treatment period should be exactly 7 days in length; however, this will not always be possible. As such, we have established acceptable visit windows for the time between each in-office vision therapy and/or phone appointment (Table 6-1). That is, the acceptable window for each appointment is ± 4 days from the original targeted date (as calculated from the initial therapy session). Furthermore, no more than two appointments can be scheduled in the same week and successive appointments must be more than 2 days apart. The visit window is –4/+7 days for each of the first two masked exams and –4/+14 days for the primary outcome masked exam. All scheduling will be performed using the CITT database.

A masked examination will be performed after 4 treatment periods, or 4 weeks of therapy, have elapsed. Therefore, the first masked examination will be scheduled on the same date as the fifth session with the Vision Therapist. Similarly, the second masked examination, which occurs 8 treatment periods after the initial therapy session, will be scheduled on the same date as the ninth session with the Vision Therapist. The Vision Therapist will meet with each subject in each group immediately after the masked exam. Therefore, for either home-based group, the appointments with the Vision Therapist, which occur at the time of the masked examinations, will be performed in person rather than by phone. This will maximize compliance and retention in either home-based group and prevent unmasking of the Masked Examiner (if only the office-
based subjects were to meet with the Vision Therapist, this could unmask the examiner). At the completion of 12 full treatment periods (i.e., approximately 12 weeks of therapy) the primary outcome (masked) examination will be performed.

Follow-up visits at 6 month and 12 month are scheduled based on the completion date of the 12 week masked examination and must occur within ± 1 month of the due date.

Table 6-1 – Treatment Visits and Masked Examinations

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<tr>
<td>7</td>
<td>3-11</td>
<td>Wk 1 phone appt.</td>
<td>Wk 1 phone appt.</td>
<td>Wk 1 VT appt.</td>
<td>Wk 1 VT appt.</td>
<td>Wk 1 VT appt.</td>
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<tr>
<td>56</td>
<td>52-63</td>
<td>Wk 8 Masked exam &amp; VT appt.</td>
<td>Wk 8 Masked exam &amp; VT appt.</td>
<td>Wk 8 Masked exam &amp; VT appt.</td>
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<tr>
<td>84</td>
<td>80-98</td>
<td>Wk 12 Primary outcome masked exam</td>
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<td>Wk 12 Primary outcome masked exam</td>
<td>Wk 12 Primary outcome masked exam</td>
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*Since initial therapy visit

Note: The overlap of successive acceptable windows is somewhat misleading because the actual scheduling software will not allow more than two subsequent vision therapy and/or phone appointments to be scheduled within the same week. In addition, subsequent appointments must be more than 2 days apart.

6.3.2 Home-based Therapy Visits

1. If the subject is randomized into either home-based group, the Site Coordinator schedules an appointment for the subject with the Vision Therapist (initial treatment appointment).

2. The therapist instructs the subject how to perform the pencil push-up procedure. In addition, for those assigned to the Home-based Pencil Push-ups with Computer VT/Orthoptics group, the therapist instructs the subject on the use of the Home Therapy System (HTS) software. The subject must demonstrate the ability to perform the procedures and to record the appropriate information on the home-log form. The subject is given a home log form to complete with the dates already entered by the Site Coordinator.

3. The subject receives a full schedule with all phone appointments and masked examinations.
4. After each phone appointment, the therapist completes the Pencil Push-up Phone Contact Form, answers questions, motivates the subject to comply with the assigned treatment and confirms the date of the next scheduled phone appointment. The form is then faxed to the DCC.
5. The subjects are scheduled for masked examinations after the completion of 4, 8 and 12 weeks of therapy.
6. The therapist is scheduled to meet with the subject in-office upon the completion of each masked examination. At each visit, the therapist obtains compliance information from the home log form and completes the Vision Therapist form. In addition, at the sessions during the active treatment phase, the subject demonstrates the pencil push-up therapy procedure and the therapist assesses progress, answers questions, and encourages the subject to adhere to the assigned treatment.
7. At the primary outcome examination (after 12 weeks of treatment) the Site Coordinator determines if the subject is asymptomatic or symptomatic (according to the mean CI Symptom Survey score). A masked examination is scheduled for 6 months for all subjects. The therapist prescribes maintenance treatment for all subjects with a mean CI Symptom Survey score less than 16 and records the assigned therapy on a Vision Therapy Record form. Subjects who are symptomatic (score \( \geq 16 \) on the CI Symptom Survey) are referred to a doctor in the clinic who is not affiliated with the CITT. This doctor assists subjects in making a decision about alternative treatments for CI. This treatment will be offered at no cost to the subject. Twelve weeks of alternative treatment must be initiated within one month after completion of the 12 week masked examination.
8. At 6 months, maintenance therapy, if applicable, is discontinued and a masked examination is scheduled for 12 months.
9. If a previously asymptomatic subject scores 16 or higher on the CI Symptom Survey at either the 6- or 12-month masked examinations, he or she is referred to a non-CITT clinician for alternative treatment. Sites may choose to offer this treatment at no cost or require payment from the subject’s family.
10. All forms associated with each visit are transmitted to the DCC by the Site Coordinator or Vision Therapist immediately following the subject’s appointment.

6.3.3 Office-based Therapy Visits

1. If the subject is randomized into either office-based group the Site Coordinator schedules an appointment for the subject with the Vision Therapist (initial treatment appointment). In addition, the Site Coordinator gives the subject a schedule containing all study visit dates.
2. At each session, the therapist performs the in-office therapy procedures for that visit according to protocol, answers questions, instructs the subject in the appropriate home therapy techniques, and motivates the subject to adhere to the assigned treatment. The subject must demonstrate the ability to complete the home therapy procedures and the home log form. The therapist also reviews the subject’s home log form and progress, completes the Therapist Form, and distributes a new home log form (after writing in the assigned home therapy procedures).
3. After 4 and 8 weeks of treatment, respectively, the masked examiner performs an examination and obtains the outcome measures.
4. After 12 weeks of treatment, the subject is scheduled for the primary outcome examination with the masked examiner.

5. At the 12-week masked examination, all subjects are scheduled for a masked examination at 6 months after the completion of active treatment. The therapist prescribes maintenance treatment for all subjects with a mean CI Symptom Survey score less than 16. The therapist records the maintenance therapy prescribed on a Vision Therapy Record form. Subjects who are symptomatic (mean CI Symptom Survey score \( \geq 16 \)) are referred to a doctor in the clinic who is not affiliated with the CITT. This doctor assists subjects in making a decision regarding alternative treatment for CI. This treatment will be offered at no cost to the subject. Twelve weeks of alternative treatment must be initiated within one month after completion of the 12 week masked examination.

6. Maintenance therapy is discontinued after the 6 month masked examination and a masked examination is scheduled for 12 months.

7. If a previously asymptomatic subject scores 16 or higher on the CI Symptom Survey at either the 6- or 12-month masked examinations, he or she is referred to a non-CITT clinician for alternative treatment. Sites may choose to offer this treatment at no cost or require payment from the subject’s family.

8. All forms associated with each visit are transmitted to the DCC by the Site Coordinator or Vision Therapist immediately following the subject’s appointment.

6.3.4 Masked Examinations at weeks 4, 8 and 12

1. The subject is greeted by Site Coordinator or Vision Therapist who inquires about issues or concerns and reminds him or her not to discuss treatment with the Masked Examiner.

2. The Masked Examiner administers the CI Symptom Survey, obtains the outcome measures, completes the Masked Examiner form, the Medication form and administers the CI Symptom Survey a second time.

3. At the 12-week visit, the parent or guardian will be asked to complete the Academic Performance form. If the parent/guardian is unavailable, the site coordinator will contact them within 5 days, by phone, to obtain the information for the form.

4. Immediately following the masked exams that occur during the active treatment phase, each subject will meet with the Vision Therapist. The therapist will collect the subject home log form, review compliance and progress, distribute new home log forms, perform any procedures indicated in the protocol (office-based groups at weeks 4 and 8 only), have the subject demonstrate any home therapy techniques, and motivate the subject to comply with the assigned treatment plan. At the 12-week visit, the Vision Therapist will assign maintenance therapy if applicable (i.e. subject is asymptomatic).

5. At the completion of each therapy session, the therapist completes the Vision Therapy Record form. At the week-12 visit, the therapy record form will be used to document the maintenance therapy assigned to asymptomatic subjects.

6. After the primary outcome examination (after 12 weeks of treatment) the Site Coordinator completes the Treatment Disposition form and schedules a 6-month follow-up visit.
7. If, at the week 12 visit, the mean CI Symptom Survey score is 16 or higher, the Site Coordinator refers the subject to a doctor in the clinic who is not affiliated with the CITT Study. This doctor assists the subject in making a decision about an alternative treatment for CI. This treatment will be offered at no cost to the subject.

8. All completed forms are transmitted to the DCC after each masked examination visit.

### 6.3.5 Long-term Follow-up Examinations at 6- and 12-months

1. At both the 6-month and 12-month masked visits all procedures will be identical to those done at the 12-week masked examination.

2. After the 6-month masked examination, maintenance therapy if applicable is discontinued for all groups and the subjects are scheduled for their final masked examination at 12 months.

3. If a previously asymptomatic subject scores 16 or higher on the CI Symptom Survey at either the 6- or 12-month masked examinations, he or she is referred to a non-CITT clinician for alternative treatment. Sites may choose to offer this treatment at no cost or require payment from the subject’s family.

### 6.4 Tracking Subjects through Treatment and Follow-up

Using the scheduling module of the CITT database, weekly updates for subjects still in study will be sent from each clinic site to the CITT Project Coordinator. This information will be sent via a secured internet connection. Included in the weekly update will be the proposed dates of all therapy visits. This information will be used by the DCC to track the progression of a subject through the 12 weeks of treatment and to update the expected visit date of each subject.

If a subject misses an appointment, the Site Coordinator will contact the subject by phone and reschedule the appointment as soon as possible. The Site Coordinator should make 3 daily calls spaced throughout the day/evening (after school hours if school is in session), to optimize the possibility of reaching the subject during the treatment window.

If contact is unsuccessful, the Site Coordinator should contact the subject/ guardian through the mail. The mailing should be made with a delivery confirmation and return signature request. If these attempts are also not successful, the Study Chair should be notified and a decision will be made on a case-by-case basis on how to proceed.
Chapter 6 Appendix
DESCRIPTION OF STUDY

1. Introduction
You have been asked to let your child take part in a national multi-center research study. The study is funded by the National Eye Institute (NEI). The NEI is a part of the National Institutes of Health, which is the federal government branch that funds medical research. The NEI has reviewed this study to make sure that the science is good. In addition, it is providing the funding for the study.

First, we want you to know that letting your child take part in this study is up to you. You may choose not to let your child take part. In addition, you may withdraw your child from the study at any time without fear of penalty or loss of vision care.

What follows is a description of the research study. Before you decide whether to let your child take part, please take as much time as you need to ask any questions of the doctor and staff. You may also want to discuss this study, with family, friends, or your family doctor.

2. Information about the Study
The eye exam that we did showed that your child has convergence insufficiency (CI). CI is an eye-teaming problem in which the eyes would like to turn out when a person is reading or doing close work. If the eyes actually turn out, the person has double vision. To stop double vision from happening one must make extra effort to make the eyes turn back in. This added effort can cause symptoms that can affect reading and working at near. These symptoms include eye strain, blurred vision, mild to moderate headaches, double vision, difficulty paying attention, and loss of place when reading or doing tasks at near.

At present, several treatments are available and different doctors suggest different treatments. Three treatments that are often used are pencil push-up therapy, computer therapy, and office vision therapy. Although commonly used, the success rates for these treatments are not known. If one treatment is better than the others is also not known. The purpose of this study is to see if any of these treatments works well and if so, which one is best.

The study will include about 208 children at 9 clinics who have CI and symptoms. Each child will receive treatment for 12 weeks. Then there will be a follow-up visit 6 months and 1 year later. Patients who do not get better after the 12-week treatment program can receive another treatment at no cost at (Name of Institution). This treatment will consist of 12 weeks of care that must be started within one month of completing the 12 week examination.
3. Study Procedures

**Treatment:** Your child qualifies for this study. If you choose to have your child take part in the study, the treatment he/she will receive will be decided at random by a computer. This is similar to flipping a coin to decide which treatment will be used. Neither you nor the doctor can choose which treatment your child receives. Your child has the same chance of receiving one of four treatments. Two treatments are done at home. They are Pencil Push-up treatment and Pencil Push-ups with Computer Vision Therapy. The other two treatments are done in the office and include home exercises. They are Vision Therapy and Placebo (like a sugar pill) Vision Therapy. You will not be told which of the office-based treatments your child received until the end of the study when all active subjects have completed the 12 month follow-up appointment.

There have been no really good research studies showing that any of these treatments work well or if one is better than the other. In fact, some people think that just visiting your doctor’s office regularly can make patients feel better and improve how their eyes feel. The placebo treatment group is included to look into this. Your doctor is not sure which treatment is better.

**Home-Based Pencil Push-up Treatment**
If your child is in the pencil push-up group, he/she will be asked to do one simple exercise at home. It will need to be done for about 15 minutes per day, 5 days per week. This therapy is like the pencil push-up treatment that would be given if your child were not a part of the study. You or your child will need to carefully record the length of time your child spends doing therapy each day and how well he/she was able to do it. There will also be a phone call each week with a therapist to discuss your child’s progress.

Your child will be seen for a brief eye exam after he/she finishes 4, 8, and 12 weeks of treatment. At the end of the 12 weeks your child will be asked to do some pencil push ups at home for the next 6 months. At the end of these 6 months, your child will then come to the office for a follow-up visit. After the 6-month visit, your child will no longer have to do any therapy at home and we will schedule the last visit 6 months later. Your child will be asked to complete a short survey at the beginning of the study and at all follow-up visits.

If your child is not better after the 12-week treatment program, another doctor at the (Name of Institution) will be able to prescribe a different treatment for your child. There will be no cost for this. Depending on the treatment given, up to 12 more weeks of treatment might be necessary.

**Home-Based Pencil Push-up Treatment with Computer Vision Therapy**
If your child is in this treatment group, he/she will be asked to do one simple exercise at home called pencil push-ups and also to use a computer program at home for therapy. The computer program will be given to you at no charge. Total therapy time to be done at home is about 20 minutes per day for 5 days per week. This therapy is like pencil push-up and computer treatment that would be prescribed by a doctor if your child were not a part of the study. You or your child will need to record the length of time your child spends doing therapy each day and how well
Parent/Guardian Informed Consent Form – Enrollment

he/she was able to do it. There will also be a phone call each week with the therapist to discuss your child’s progress.

Your child will be seen for a brief eye exam after he/she finishes 4, 8 and 12 weeks of treatment. After 12 weeks of treatment your child will be asked to do some pencil push-ups and computer therapy at home for the next 6 months. At the end of these 6 months, your child will then come to the office for a follow-up visit. After the 6-month visit, your child will no longer have to do any exercises at home and we will schedule the last visit 6 months later. Your child will be asked to complete a short survey at the beginning of the study and at all follow-up visits.

If your child is not better after the 12-week treatment program, another doctor at the (Name of Institution) will be able to prescribe a different treatment for your child. There will be no cost for this. Depending on the treatment given, up to 12 more weeks of treatment might be necessary.

Office-Based Vision Therapy
Your child may be assigned to one of two vision therapy treatments given in the office. Children in these groups will need to come to the doctor’s office for 12 weeks in a row for a one-hour vision therapy visit. During these visits, a vision therapist will guide your child through 3 to 5 therapy procedures. In addition, they will talk about the home exercises and help with any problems your child may have. Your child will also have to do home therapy for about 15 minutes per day, 5 days per week. You will need to record the length of time your child spends doing therapy each day and how well she/he does.

Your child will be seen for a brief eye exam after finishing 4, 8 and 12 weeks of treatment. After 12 weeks of treatment your child will be asked to do a small amount of vision therapy at home for the next 6 months. At the end of these 6 months, your child will then come to the office for a follow-up visit. After the 6-month visit, your child will no longer have to do any therapy at home and we will schedule the last visit 6 months later. Your child will be asked to complete a short survey at the beginning of the study and at all follow-up visits.

If your child is not better after the 12-week treatment program, another doctor at the (Name of Institution) will be able to prescribe a different treatment for your child. There will be no cost for this. Depending on the treatment given, up to 12 more weeks of treatment might be necessary.

Follow-up Visits
The study will last a total of about 15 months. The visit schedule is about the same that a child with CI would receive for the treatments if he or she were not part of this study.

- Weekly office visits for 12 weeks are needed for the two office-based treatment groups.
- Office visits are needed after 4, 8, and 12 weeks of treatment have been completed for the two home therapy groups.
- Weekly phone calls are needed for patients in the two home therapy treatment groups.
- Follow-up visits, 6- and 12-months from the end of the 12-week treatment program are needed for all 4 groups.
**Parent/Guardian Informed Consent Form – Enrollment**

Brief eye exams will be done after 4, 8, and 12 weeks of treatment. Then, brief eye exams will be done 6 and 12 months later. These are like exams that would be done if your child were not a part of the study.

- The testing by your child’s doctor will include tests of vision, focusing, and eye teaming.
- At the follow-up visits, another doctor who does not know which treatment your child is receiving will do the testing.

Because this study lasts for 15 months, it is very important that we can stay in touch with you.

- You will be asked to give us your contact information.
- If you move or your health plan changes, we will transfer your care to another doctor so your child can stay in the study.
- You are also saying it is OK to use the information you have given us to try to find you if we lose contact with you.

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<thead>
<tr>
<th>SUMMARY OF THE STUDY</th>
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<tbody>
<tr>
<td>1. Before your child can be part of this study, everything will be explained to you and your child. If you agree to have your child take part you will be asked to sign this form.</td>
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<tr>
<td>2. A computer will decide which of the four treatments your child will receive. The four treatments are Pencil Push-up therapy at home, Pencil Push-up with Computer Vision Therapy at home, Vision Therapy in the office, and Placebo Vision Therapy in the office.</td>
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<td>3. For the treatments done in the office, your child will need to come to the doctor’s office for 12 weeks in a row for 60 minutes.</td>
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<tr>
<td>4. For the treatments done at home, your child will need a weekly phone call with the therapist. Your child will also need to come to the doctor’s office after 4, 8, and 12 weeks of treatment.</td>
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<tr>
<td>5. After 4, 8, and 12 weeks of treatment, and at the 6- and 12-month follow-up visits, your child’s eyes will be tested by an eye doctor who does not know which treatment your child received. At these visits, your child’s vision, eye teaming, and eye focusing will be checked. Your child will also be given a short survey to fill out.</td>
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<tr>
<td>6. If there is not a lot of improvement in your child’s eye condition after the 12-week treatment program, he/she will be sent to another doctor in the clinic who can give 12 weeks of a different treatment at no cost.</td>
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**4. Alternative Treatments**

Your child needs treatment for CI. You do not have to let your child take part in this study for your child to receive treatment. Your child can receive treatment without being in the study. There are no other treatments that have been shown to be as good as or better than those in this study.

**5. Risks**

The risks associated with the treatments are the same whether your child has treatment as part of the study or not. For each treatment these could be a possible increase in symptoms such as headaches, eyestrain, blurred vision, or double vision. There are no known serious or long-lasting risks.
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Although we have tried to list all possible risks and discomforts, there may be others that we do not know about at this time. However, these unknown risks would be the same whether your child received treatment as part of this study or not.

6. Benefits
Your child will receive 12 weeks of treatment and any required equipment at no cost. If your child is not better after the 12-week treatment program, another doctor at the (Name of Institution) will be able to give your child a different treatment. There will be no cost for this. Depending on the treatment given, up to 12 more weeks of treatment might be necessary.

The information gained from this study will be very important for doctors to treat children with CI in the future. Your child may not directly benefit from taking part in this study. However, the results of this study may directly affect the eye care of children who develop CI in the future.

7. Confidentiality
All data from the study will be kept confidential in a separate record of your child’s visits. A copy of the data will be kept and evaluated at a central Data Coordinating Center at The Ohio State University. At no time will the Data Coordinating Center know your child’s name, since all data kept there will be by patient ID number only. However, 100% confidentiality cannot be promised, as research records can be asked for by court order.

Results of the study will be reported in vision journals and may be presented at meetings. However, at no time will any patient in the study be identified.

Our Site Coordinator will have the contact information that you give us in case we need to contact you.
• If you move, you will be asked to provide your new contact information.
• At times you may receive a phone call from the Site Coordinator to check on your child’s eyes and to see if you have any questions. You will be called at the times that you said were best for you. If you are not available at the time of the call and would like to call the Site Coordinator yourself, we will give you his/her phone number.
• You will also be able to use this number should you have any questions at any time.
• If we are not able to locate you when we try to schedule your child’s follow-up visits, we will try to contact you through the other information you have given us.

8. Costs and Compensation
All visits for the study and any required vision therapy equipment are free of charge. In addition, to cover time and travel costs, children who come in to the office for treatment will be given $20 for each therapy visit attended. The children in the two home based groups will receive $20 for each scheduled phone call that is completed. Therefore, the compensation is the same in all 4 treatment groups. In addition, you will be given $50 per visit for the 3 follow-up exams. This includes the exam after 12 weeks of treatment have been completed and the 6-month and 12-month exams.
Chapter 6 Enrollment and Study Visits

Parent/Guardian Informed Consent Form – Enrollment

Payment will be made directly to you. Payments will occur at three times. These are after your child finishes the follow-up exam at the end of the 12 weeks of treatment, after the 6-month follow-up exam, and after the 12-month follow-up exam.

9. Research-Related Injuries
It is unlikely that your child would be physically injured by being in this study. However, if this were to happen, medical treatment is available, but you or your insurance company must pay for the treatment. There are no payments for lost wages and/or direct or indirect losses. The (Name of Institution) will not pay for medical costs or for research-related injuries. Further information about research-related injuries is available from the (Name of IRB Chair) (Office of the Institutional Review Board) at (IRB Chair Telephone).

10. Right to Refuse or Withdraw
You understand that if you do not let your child take part in this study your child can still get eye care at the (Name of Institution). You know that you are free to change your mind; your child can quit this study at any time and no one will hold it against you.

11. Questions
(Name of PI) is in charge of this study at (Name of Institution). If your child has discomfort or other symptoms, or you have any other questions about the study, (Name of PI) can be reached at the following numbers (PI Telephone). (Name of study coordinator), our study coordinator, can be reached at (telephone #). If (Name of PI) or (name of study coordinator) cannot be reached or if there is an emergency, the (Name of Institution) can be reached at the following emergency number: (Emergency telephone).

You have been given the chance to ask questions. All of your questions have been answered to your liking. You have also been given the chance to talk with any person outside of (Name of Institution) and to ask his/her opinion and recommendations.

If you have questions about your child’s rights as a research subject, you should call the person in charge of the Institutional Review Board administrator (Name of IRB Chair) (IRB Chair Telephone).

You understand that the treatments in this study are not guaranteed to improve your child’s CI.

12. Your Obligation to the Study
As said before, your child’s taking part in this study is voluntary. If you decide to let your child to take part, you can quit the study at any time and request that we no longer contact you.

However, You should not have your child take part in the study unless you 1) are willing to have your child receive any of the four treatments, 2) are willing to bring your child to the office for 12 weeks in a row of treatment, and 3) your child is willing to do about 15 minutes of home
therapy for 5 days per week for a 12 weeks. In addition, you must be willing to bring your child in for a 6-month and 12-month follow-up visit.

If you have any doubts about this or any questions about the study now or in the future, you should speak with (Name of PI) (PI Telephone) or (name of Study Coordinator) (SC telephone).

Please keep a copy of this document in case you want to read it again. You will be given a signed and dated copy of this form to keep.

Your signature, below, will mean that you have decided for your child to take part in this research study. It also means that you have read and understand the information above.

Patient's Name Printed ____________________________
Parent/Guardian Name Printed ___________________________

_________________________  ______________
Parent/Guardian Signature      Date

_________________________  ______________
Investigator’s Signature      Date
Reading Level 7.1

Child Assent Form - Enrollment
(Name of Institution)
The Convergence Insufficiency Treatment Trial (CITT)

Purpose of the Study: You have an eye problem called convergence insufficiency or CI. CI is an eye-teaming problem where the eyes would like to turn out when reading or doing close work. If the eyes really turn out, double vision happens. To stop double vision from happening one must try hard to make the eyes turn back in.

You have been asked to be part of a large study called the Convergence Insufficiency Treatment Trial (CITT). The idea of this study is to figure out the best treatment for CI. The study will include about 208 children, just like you, across the United States.

Treatment: There are four treatments in this study. The treatment that you get is decided at random by a computer. This is similar to flipping a coin to decide. You, your parents, or the doctor does not get to pick the treatment. You have a 25% chance of receiving one of the 4 treatments. Two treatments are done at home. They are Pencil Push-ups and Pencil Push-ups with Computer Vision Therapy. The other two treatments are done in the office. They are regular vision therapy and control (placebo, like a sugar pill) vision therapy.

Some of the kids in this study will get the treatments that are done at home. Pencil push-up is the name of the main home treatment. For pencil push-ups, you would have to practice at home 5 days per week for 15 minutes and talk with a therapist once a week on the phone. The second treatment done at home is the same except that you also do computer therapy at home.

The third and fourth treatments are done in the doctor’s office and at home. With these treatments you would have to come to the office once every week for about 1 hour. During each visit you would work with a therapist and practice 3 to 5 exercises. You will also have to practice some exercises at home for 15 minutes each day for 5 days per week. The treatments done in the office are regular vision therapy and control group vision therapy. The control group treatment looks like vision therapy but may not really help. This control treatment also cannot hurt you in any way.

No matter which group you are in, you will be checked after 4, 8, and 12 weeks of treatment are done. This exam will be done by a doctor who does not know which treatment group you are in. After the 12-week treatment program, you will still do a small amount of therapy at home for 6 more months. Then, the doctor will check your eyes again. For the next 6 months you will not have to do any therapy; after that, there will be one more check up 6 months later.

If the treatment doesn’t work a doctor will talk with you and your parent. At that time, it can be decided what to do next to make you feel better.
**Benefits:** You will get free treatment for your CI. There is no guarantee that the treatment will help you personally. However, the results from this study may help other kids who have CI in the future. If the treatment you get does not work for you, you will be given another 12 weeks of treatment at no cost.

**Risks:** The eye tests are just like regular eye tests that you would get even if you were not in the study. There is a very small chance that your eyes may feel tired or strained during testing. You might also get tired eyes and possibly headaches when you do any of the four treatments. However, you understand that the testing and therapy will not do anything that can hurt you in any way.

**Confidentiality:** The doctors and therapists will not tell anyone except for your parents the results of your eye tests and treatment. Also, a code number will always identify you so the people who work where all the results are sent will never know your name.

You know that you do not have to be in this study. Also, you can refuse to be part of the study at any time. If you join the study, you can also change your mind later if you want and still be treated by a doctor outside of the study.

However, you should not agree to take part in the study unless you: 1) are willing to receive any of the four treatments, 2) are willing to come in for 12 weeks in a row for treatment and a 6-month and 12-month follow-up visit, and 3) can do approximately 15 minutes of home therapy for 5 days per week for a 12-week period.

**Questions:** If you or your parents have any questions, you can call the doctor in charge (Name of PI) at (PI Telephone) or (Name of coordinator) at (SC telephone). You may also call (Name of IRB Chair) who watches over the research projects at (Name of Institution) at (phone number).

You have been given a chance to ask all the questions you have, and all of your questions have been answered. Again, the research project is voluntary and if you do not want to be in it, you do not have to. **However, if you want to be in the project it is very important that you do all of the therapy at home that is prescribed for you. Also, you must make sure that you come to the doctor’s office for all of your follow-up visits.**

If you sign below it means that you have decided to volunteer as a research subject for this CITT project and that you have read the information written above.

Patient’s Name Printed ____________________________  
______________________________________  ______________
Patient Signature       Date

_______________________________________  ______________
Investigator’s Signature       Date