Study Title: The Emmetropization Via Accommodation (EVA) Study

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The Ohio State University Combined Parental Permission and HIPAA Authorization for Child's Participation in Research

Study Title:	**Emmetropization Via Accommodation (EVA) Study TREATMENT PHASE**
Principal Investigator:	**Ann Morrison, OD, PhD**
Sponsor:	**The Ohio State University College of Optometry**

- **This is a parental permission form for research participation.** It contains important information about this study and what to expect if you permit your child to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to permit your child to participate.
- **Your child's participation is voluntary.** You or your child may refuse participation in this study. If your child takes part in the study, you or your child may decide to leave the study at any time. No matter what decision you make, there will be no penalty to your child and neither you nor your child will lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you or your child is a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **Your child may or may not benefit as a result of participating in this study.** Also, as explained below, your child's participation may result in unintended or harmful effects for him or her that may be minor or may be serious depending on the nature of the research.
- **You and your child will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you permit your child to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider permitting your child to participate in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not your child should be a part of this study. More detailed information is listed later in this form.

The purpose of this study is to determine if glasses and eye focusing exercises can help babies who are more farsighted than normal at 2 months of age undergo a normal process called emmetropization, which does not always happen in highly farsighted infants. The study is expected to last 15 months and may require your child to wear glasses. There will be a total of seven scheduled visits. There are no major risks of the study, but your child will be dilated at each of their visits. The major benefits of the study is that subjects will receive free eye care for the duration of the study and will receive glasses at no cost, if they are given to your child.

If you do not wish to participate in the study, a referral can be made to another eye are provider.

1. Why is this study being done?

Babies are normally born far-sighted and their eyes undergo a process called emmetropization. Emmetropization is when the eye grows longer during development, so that babies lose their far-sightedness. Sometimes, babies that are more farsighted than normal do not undergo the normal emmetropization process. The purpose of this project is to determine if emmetropization, a normal process that does not always occur in highly farsighted infants can be enhanced by prescribing glasses and performing basic eye focusing exercises at home.

2. How many people will take part in this study?

A total of 30 subjects will be randomized to either treatment or observation in the study. Half of the subjects, that qualify for randomization (≥+5.00 D - ≤+7.00 D) will be randomized to placebo (no-treatment) and the other half will be randomized to partial correction, like flipping a coin. Babies that have a prescription higher than the randomization group (>+7.00 D) will be enrolled in a Case Series and all will receive treatment. Up to 10 babies will enrolled in the Case Series.

3. What will happen if my child takes part in this study?

We will randomize subjects to a treatment group or a placebo group. If the subject is randomized to the treatment group, we will prescribe glasses with a partial correction, an amount that is less than their full degree of farsightedness but may be enough to put them in the zone of ‘effective emmetropization’. This "boost" is meant to enable very farsighted babies to use their eyes in a normal way and emmetropize as infants do who are not highly farsighted. This partial correction would be given at 3 months of age. As changes in farsightedness occur, the power of the glasses will be reduced at follow-up visits to keep the farsightedness within the target zone of effective emmetropization. If an infant reaches a normal amount of farsightedness during the study, glasses will be discontinued. The comparison group will be farsighted babies who receive the current standard care, namely no correction but regular monitoring. The main outcome of the study will be whether there is a significant difference in the decrease of farsightedness between the two groups when the infants are 18 months of age.

This study will require multiple visits over an 18 month period. Seven visits will be scheduled at the following months of age: baseline (3 months), 4 ½, 6, 9, 12, 15, and 18 months of age. Each visit will last 1-2 hours and will include drops that will numb the eye and will temporarily make the pupil large (pupil dilation) and prevent the eyes from being able to focus up close (cycloplegia) which will allow for better measurements of the eye. The refractive error (prescription) of the subjects’ eyes will be measured while looking

straight ahead and while looking off to the side multiple times. The subjects' focusing ability (accommodation), ocular health, and eye alignment will be assessed at every visit.

4. How long will my child be in the study?

The study will last for 15 months.

5. Can my child stop being in the study?

Your child may leave the study at any time. If you or your child decides to stop participation in the study, there will be no penalty and neither you nor your child will lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can my child expect from being in the study?

The risks, side effects, or discomforts that may be experienced in this study are the same ones associated with a normal eye examination. The drops used to make your child's pupil large may cause glare and blurred vision at close distances on the day of testing. The blur when reading and sensitivity to bright lights from the dilation typically last for 2 to 7 hours. Your child will receive sunglasses for comfort.

7. What benefits can my child expect from being in the study?

Your child's high amount of farsightedness may decrease which would decrease the visual burden of the subject and potentially reduce the risk of developing strabismus (crossed eyes) or amblyopia (lazy eye).

8. What other choices does my child have if he/she does not take part in the study?

You may choose not to have your child participate without penalty or loss of benefits to which you are otherwise entitled.

You may take your child to another optometrist or ophthalmologist for a consultation or treatment. You or your child may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

Costs of taking part in this study are the ordinary time and travel expenses of coming to an appointment at The Ohio State University College of Optometry.

10. Will I or my child be paid for taking part in this study?

You will be given $40 cash for each visit at the conclusion of the visit. If your child is randomized to the glasses correction arm of the study, frames and lenses will be provided to you. If the lenses have to be changed during the study, this will also be provided.By law, payments to subjects are considered taxable income.

11. What happens if my child is injured because he/she took part in this study?

If your child suffers an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if your child should obtain medical treatment at The Ohio State University Medical Center, Riverside Pediatric Associates, or The Ohio State University College of Optometry.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my child's rights if he/she takes part in this study?

If you and your child choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights your child may have as a participant in this study.

You and your child will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You or your child may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my child's de-identified information (and bio-specimens) be used or shared for future research?

Yes, it/they may be used or shared with other researchers without your additional informed consent.

14. Will my child's study-related information be kept private?

Efforts will be made to keep your child's study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your child's participation in this study may be disclosed if required by state law.

Also, your child's records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If we find information that significantly impacts your child's health, we **will** share it with you. This would include any abnormal findings on health examinations or during screening.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information about my child may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your child's study visits;
- Information that includes personal identifiers, such as your child's name, or a number associated with your child as an individual;

II. Who may use and give out information about your child?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that your child is participating in a research study and have access to your child's information;
- If this study is related to your child's medical care, study-related information may be placed in your child's permanent hospital, clinic or physician's office record;
- Others: staff members and doctors practicing at Riverside Pediatric Associates..

IV. Your child's information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your child's information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. The authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your child's health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, your child will not be able to stay in this study. When you withdraw your permission, no new health information

identifying your child will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my child's health information?

Then your child will not be able to be in this research study and receive research-related treatment. However, if your child is being treated as a patient here, your child will still be able to receive care.

IX. Is my child's health information protected after it has been given to others?

There is a risk that your child's information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my child's information?

Signing this authorization also means that you may not be able to see or copy your child's study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel your child has been harmed as a result of study participation, you may contact**:**

Donald O. Mutti, OD, PhD
OSU Study Key Personnel
338 West 10th Avenue
Columbus, OH 43210-1240
Phone: 614-247-7057
Email: mutti.2@osu.edu

Ann Morrison, OD, PhD
OSU Clinic Site Principal Investigator
338 West 10th Avenue
Columbus, OH 43210-1240
Phone: 614-247-0010
Email: morrison.421@osu.edu

For questions related to your child's privacy rights under HIPAA or related to this research authorization, please contact*:*

Cathy Beatty
College of Optometry Privacy Officer
338 West 10th Avenue
Columbus, OH 43210-1240

Phone: 614-247-6190
Email: beatty.22@osu.edu

For questions about your child's rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If your child is injured as a result of participating in this study or for questions about a study-related injury, you may contact**:**

Donald O. Mutti, OD, PhD
OSU Study Key Personnel
338 West 10th Avenue
Columbus, OH 43210-1240
Phone: 614-247-7057
Email: mutti.2@osu.edu

Ann Morrison, OD, PhD
OSU Clinic Site Principal Investigator
338 West 10th Avenue
Columbus, OH 43210-1240
Phone: 614-247-0010
Email: morrison.421@osu.edu

Signing the parental permission form

I have read (or someone has read to me) this form and I am aware that I am being asked to provide permission for my child to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to permit my child to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	
Printed name of person authorized to provide permission for subject	**Signature of person authorized to provide permission for subject**
Relationship to the subject	**Date and time** **AM/PM**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	Date and time **AM/PM**

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	Date and time **AM/PM**
Printed name of witness	**Signature of witness**
	Date and time **AM/PM**