Informed Consent Form for Clinical Research

(Child Version: Must be signed by children aged ≥8 years old themselves)

Hello!

Would you like to participate in a research study titled "Multicenter, Open-Label, Parallel-Group, Randomized Controlled Study Comparing the Dose-Response Relationship of LED Red Light in Controlling Myopia Progression"? The vision rehabilitation instrument used in this study has obtained the Medical Device Registration Certificate of the People's Republic of China. Before participating in the study, you need to discuss it with your parents/guardians. Meanwhile, doctors or nurses will explain the study to you and answer all your questions. If you have any questions at any time, you can contact the research doctor.

1. Why is this study being conducted?

China has one of the highest myopia prevalence rates among adolescents in the world, with the prevalence exceeding 50% among adolescents living in large cities. According to a survey by the World Health Organization (WHO), myopia has become one of the main causes of visual impairment globally. It is estimated that by 2050, 50% of the global population will be myopic, including 10% with high myopia. High myopia is associated with a significant increase in blindness and blinding eye diseases due to fundus abnormalities. Therefore, controlling myopia progression to prevent high myopia and reduce the burden of blinding eye diseases on individuals and society is an urgent public health issue.

The earlier myopia occurs, the more likely it is to develop into high myopia. Myopia prevention and control measures need to be implemented as early as possible. In clinical studies on red light for controlling myopia progression in children published in the past 3 years, it has been confirmed that low-level red light can effectively control the elongation of myopic axial length. This study will explore the effectiveness and safety of non-laser PBM therapy combined with defocus lens therapy under different intervention durations.

2. What will be done to me?

The study is expected to last from November 2025 to December 2026, and approximately 50 children will be enrolled at this center. The study is divided into 4 groups, and subjects will be randomly assigned to each group. After the study starts, doctors will perform some eye examinations on you, including visual acuity test, slit lamp examination, etc. Each participant will return to the

hospital for follow-up visits at 1 month, 3 months, 6 months, 9 months, and 12 months after enrollment. The intervention measures are: ① Myopia defocus lenses (Hoya DIMS); ② Vision rehabilitation instrument. All groups will receive the first intervention; the second intervention depends on the result of randomization. All examinations and follow-up visits are non-invasive. This trial is an open-label, non-blinded study (patients, parents, physicians, examiners, and researchers all know which group the patient belongs to) lasting for 12 months.

- Inclusion Criteria:

Adhering to the principles of fairness, respect, and maximizing benefits for subjects, ensuring safety and health, and minimizing harm as much as possible.

1) Aged 6 to 14 years old, regardless of gender;
2) After cycloplegic autorefraction, monocular or binocular spherical equivalent refraction (SER) meets: -6.00D ≤ SER ≤ -1.00D, and binocular best-corrected visual acuity (BCVA) ≥ 0.8 (logMAR 0.1; Snellen 20/25);
3) Binocular anisometropia ≤ 1.50D;
4) Able to understand the purpose of the study, willing to participate in this clinical verification, sign the informed consent form personally or through their legal guardian, and cooperate with the entire trial process (12 months).

- Exclusion Criteria:

1) Photophobia or allergy to cycloplegic agents (e.g., tropicamide or cyclopentolate);
2) Received any of the following myopia control measures within one month (including but not limited to): low-concentration atropine eye drops, orthokeratology lenses, myopia control-related frame glasses, low-level red light therapy, defocus soft contact lenses, or defocus RGP lenses;
3) Subjects with ocular diseases that may affect visual acuity or refractive error (e.g., lens disorders such as cataracts, glaucoma, macular degeneration, corneal diseases, uveitis, retinal detachment, severe vitreous opacity, etc.);
4) Neurological diseases (previous convulsion history, epilepsy, tic disorders, central nervous system developmental abnormalities) or mental and psychological diseases;
5) Systemic diseases: immune system diseases, central nervous system diseases, Down syndrome, asthma, severe cardiopulmonary function impairment, severe liver and kidney dysfunction,

acute or chronic sinusitis, or diabetes mellitus;

6) Binocular manifest strabismus or any other pathological changes of the eyeball or acute inflammatory ocular diseases;

7) Subjects deemed inappropriate by the investigator.

- Specific Treatments:

1) Group D: Wear myopia defocus lenses (Hoya DIMS, Japan);

2) Groups A, B, and C: In addition to wearing the same brand of customized lenses (Hoya DIMS), receive ocular treatment with a vision rehabilitation instrument. The treatment durations with the vision rehabilitation instrument for the three groups are 2, 3, and 4 minutes respectively.

3. What do I need to cooperate with?

You need to cooperate in a series of eye examinations. You need to return to the hospital for re-examination at the specified time points: 1 month, 3 months, 6 months, 9 months, and 12 months during the continuous treatment.

All subjects need to wear defocus frame glasses all day long. If you are randomly assigned to Group A, B, or C, you also need to use the vision rehabilitation instrument twice a day, with an interval of 4 hours or more. If you experience any discomfort in the eyes or the whole body, you need to inform your parents immediately so that they can communicate with the research physician or designated contact person in a timely manner.

4. What benefits will I get from participating in this study?

During the study, your myopia may still progress. However, it is also possible that your axial length may be partially shortened, your myopic refractive error may be reduced, and the choroid of the fundus (which thins due to myopia) may be thickened. In addition, you will receive free treatment and examinations. The vision rehabilitation instrument and defocus lenses used during the study are provided free of charge. Moreover, you will receive a transportation allowance of 100 yuan per visit for returning to the hospital for examinations as required by the study.

5. What adverse reactions, risks, and discomfort may I face if I participate in this study?

Adverse reactions may include short-term adaptation to wearing glasses, which usually lasts for 1 week to 1 month. This adaptation is caused by differences in magnification, face curvature, pantoscopic angle, etc. between the new glasses and your previous old glasses. It is also possible to experience afterimages due to temporary light exposure (a temporary decrease in visual acuity and

pink shadows that persist after closing the eyes; however, they will gradually decrease and disappear over time). In addition, there is a very low risk of macular damage to the fundus due to individual differences and unknown factors associated with red light therapy. If you experience decreased visual acuity, please inform your parents immediately so that they can contact the doctor for re-examination.

6. Must I participate in this study?

Your participation in this study is voluntary. You can continue to use your regular glasses or other methods to intervene in myopia, or ask the doctor for other treatments/medications. After participating in the study, you can withdraw from the study at any time if you change your mind. Whether you participate in this study or not, your doctor will provide you with the best medical care.

7. Will my personal information be disclosed?

All your relevant data (including personal information, medical records, etc.) during the study will be completely stored in the hospital. Only your attending doctor, researchers, or the Ethics Committee are allowed to access the above data; no other personnel can access them. Any public reports on the results of this study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical data to the extent permitted by law.

8. Who should I contact if I have any questions?

If you have any questions or concerns about this study, you can contact Dr. Zhang, who is in charge of the study (phone number: 18939916192). If there is any important new information during the study that may affect your willingness to continue participating in the study, the above doctor will also communicate with you in a timely manner.

9. What should I do now?

Read this document with your parents, discuss its content with them, and ask your questions. Also, discuss with your doctor or nurse to confirm that you are willing to participate in the study and understand what you need to do next.

Subject's Statement

The doctor has explained all aspects of this study to me in detail, and I have asked the doctor about any words or terms I did not understand. I understand that participating in this study is voluntary.

After careful consideration, I am willing to participate in this study and cooperate with the doctor's diagnosis, treatment, and follow-up. I will promptly inform my parents/guardians or the doctor if I feel unwell.

I understand that I can stop participating in this study at any time, and the doctor will help me receive other treatments.

Subject's Full Name (in block letters): _____ Date: ___/ ___ / ___

Subject's Date of Birth: ____/ ___ / ___

Investigator's Statement

I have explained all aspects of this study to the subject to the maximum extent of their understanding and answered all their questions. Their decision to participate is voluntary.

Investigator's Full Name (in block letters): _____ Date: ___/ ___ / ___

Informed Consent Form for Clinical Research

(Guardian Version: Must be signed by all guardians of minors)

Dear Patient and Family Members,

We invite you to participate in a clinical research study titled "Multicenter, Open-Label, Parallel-Group, Randomized Controlled Study Comparing the Dose-Response Relationship of LED Red Light in Controlling Myopia Progression". The vision rehabilitation instrument used in this study has obtained the Medical Device Registration Certificate of the People's Republic of China. Before deciding whether to participate in this study, please carefully read the following content, which will help you understand the study purpose, content, protocol, duration, as well as the potential benefits, risks, or discomfort that may result from participating. You may discuss this with your relatives and friends, or ask the doctor for a more detailed explanation to assist you in making a decision about joining this clinical research.

1. Why is this study being conducted?

China has one of the highest myopia prevalence rates among adolescents in the world, with the prevalence exceeding 50% among adolescents living in large cities. According to a survey by the World Health Organization (WHO), myopia has become one of the main causes of visual impairment globally. It is estimated that by 2050, 50% of the global population will be myopic, including 10% with high myopia. High myopia is associated with a significant increase in blindness and blinding eye diseases due to fundus abnormalities. Therefore, controlling myopia progression to prevent high myopia and reduce the burden of blinding eye diseases on individuals and society is an urgent public health issue.

The earlier myopia occurs, the more likely it is to develop into high myopia. Myopia prevention and control measures need to be implemented as early as possible. In clinical studies on red light for controlling myopia progression in children published in the past 3 years, it has been confirmed that low-level red light can effectively control the elongation of myopic axial length. This study will explore the effectiveness and safety of non-laser PBM therapy combined with defocus lens therapy under different intervention durations.

2. What are the main content and protocol of this study?

The study is expected to last from November 2025 to December 2026, and approximately 50 subjects will be enrolled at this center. The study is divided into 4 groups, and subjects will be

randomly assigned to each group. Each participant will return to the hospital for follow-up visits at 1 month, 3 months, 6 months, 9 months, and 12 months after enrollment. The intervention measures are: ① Myopia defocus lenses (Hoya DIMS); ② Vision rehabilitation instrument. All groups will receive the first intervention; the second intervention depends on the result of randomization. All examinations and follow-up visits are non-invasive. This trial is an open-label, non-blinded study (patients, parents, physicians, examiners, and researchers all know which group the patient belongs to) lasting for 12 months.

- Inclusion Criteria:

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4) Binocular anisometropia ≤ 1.50D;
5) Able to understand the purpose of the study, willing to participate in this clinical verification, sign the informed consent form personally or through their legal guardian, and cooperate with the entire trial process (12 months).

- Exclusion Criteria:

1) Photophobia or allergy to cycloplegic agents (e.g., tropicamide or cyclopentolate);
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3) Subjects with ocular diseases that may affect visual acuity or refractive error (e.g., lens disorders such as cataracts, glaucoma, macular degeneration, corneal diseases, uveitis, retinal detachment, severe vitreous opacity, etc.);
4) Neurological diseases (previous convulsion history, epilepsy, tic disorders, central nervous system developmental abnormalities) or mental and psychological diseases;
5) Systemic diseases: immune system diseases, central nervous system diseases, Down syndrome,

asthma, severe cardiopulmonary function impairment, severe liver and kidney dysfunction, acute or chronic sinusitis, or diabetes mellitus;

6) Binocular manifest strabismus or any other pathological changes of the eyeball or acute inflammatory ocular diseases;

7) Subjects deemed inappropriate by the investigator.

- Specific Treatments:

1) Group D: Wear myopia defocus lenses (Hoya DIMS, Japan);

2) Groups A, B, and C: In addition to wearing the same brand of customized lenses (Hoya DIMS), receive ocular treatment with a vision rehabilitation instrument. The treatment durations with the vision rehabilitation instrument for the three groups are 2, 3, and 4 minutes respectively.

3. What do you need to cooperate with if you participate in this study?

You need to cooperate in the following examinations: visual acuity test, pupillary height and interpupillary distance measurement, slit lamp eye examination, axial length examination, fundus examination, eye position examination, cycloplegic refraction, corneal curvature examination, fundus optical coherence tomography (OCT), and intraocular pressure (IOP) measurement. During the continuous treatment, you need to return to the hospital for re-examination of the above parameters at the specified time points: 1 month, 3 months, 6 months, 9 months, and 12 months. Additional examinations or increased frequency of follow-up visits and records may be arranged based on your child's usage feedback.

You need to truthfully inform the research team of your child's age, gender, current and past ocular and systemic health status, and sign a written informed consent form.

All subjects need to wear defocus frame glasses all day long. If your child is randomly assigned to a treatment group, they also need to use the vision rehabilitation instrument twice a day, with an interval of 4 hours or more. If your child experiences any discomfort in the eyes or the whole body, you must promptly communicate with the research physician or designated contact person.

4. What potential benefits may you obtain from participating in this study?

During the study, your child's myopia may still progress. However, it is also possible that their axial length may be partially shortened, their myopic refractive error may be reduced, and the fundus choroid that has thinned due to myopia may be thickened.

5. What adverse reactions, risks, and discomfort may be encountered if participating in this

study?

The lenses are non-medical products, but wearing new glasses may cause dizziness and require an adaptation period of approximately 1 week to 1 month. After using the vision rehabilitation instrument, afterimages may occur and last for about 10 minutes. In addition, there is a very low risk of macular damage to the fundus due to individual differences and unknown factors associated with red light therapy. It is necessary to monitor your child's visual acuity and conduct regular follow-up visits. If macular damage is suspected, please promptly contact the research doctor.

6. Are there any alternative treatment options if you do not participate in this trial?

You may choose not to participate in this study, which will not have any adverse impact on your child's access to conventional treatment. Current conventional interventions for correcting and controlling myopia include: orthokeratology lenses, atropine eye drops, etc.

7. Can you request to withdraw midway if you choose to participate in this study?

Participation in the study is entirely voluntary. You may refuse to participate or request to withdraw from the study at any time during the process. This will not affect your relationship with the doctor or your child's normal treatment.

8. What are the expected costs of participating in the trial? Are there any other compensations?

Free treatment and examinations are provided for each subject. The vision rehabilitation instrument and defocus lenses used during the study are free of charge. In addition, you will receive a transportation allowance of 100 yuan per visit for returning to the hospital for examinations as required by the study.

9. What treatment and/or compensation may subjects receive in case of trial-related injuries?

If a subject suffers clinical trial-related injuries, they can receive timely communication and treatment by contacting the research physician and the hospital where the study is conducted. Compensation may be obtained through insurance (if eligible under the insurance terms). For treatment costs of injuries beyond the scope of clinical trial insurance compensation, the clinical trial collaborator providing the product will provide timely compensation and cover the costs of necessary treatment, so as to minimize the clinical trial risks and economic losses.

10. Under what circumstances will the trial be terminated?

You may be required to withdraw from the study if your child needs to receive other treatments, fails to comply with the trial requirements, suffers trial-related injuries, or for any other reason

deemed necessary by the research doctor. The study may be terminated if 30% of subjects have poor treatment effects, but follow-up visits will be conducted thereafter. If you withdraw from the trial for any reason, the research doctor may request additional examinations for your child.

11. Will personal information be disclosed if you participate in this study?

All relevant data of your child during the study (including personal information, medical records, etc.) will be completely stored in the hospital and only accessible to research personnel. Monitors, auditors, Institutional Review Board (IRB)/Independent Ethics Committee (IEC), and regulatory authorities are permitted to access the original medical records of subjects within the scope allowed by applicable laws and regulations without violating the privacy of subjects. Any public reports on the results of this study will not disclose your child's personal identity. We will make every effort to protect the privacy of your child's personal medical data to the extent permitted by law.

12. Who can you contact if you have any questions during the study?

If you have any questions or concerns about this study, you can contact Dr. Wang, who is in charge of the study (phone number: 18939916192). If there is any important new information during the study that may affect your willingness to continue participating, the above doctor will also communicate with you in a timely manner.

13. Other Notes

The decision to participate in this study is entirely up to you (and your family). Before making a decision, please feel free to ask the doctor any questions you may have.

Thank you for reading the above materials. If you decide to participate in this study, please inform your doctor, who will arrange all matters related to the study for you.

Guardian's Statement

I have carefully read this informed consent form, have had the opportunity to ask questions, and all my questions have been answered. I understand that participating in this study is voluntary. I may choose not to let my child participate in this study, or withdraw by notifying the researcher at any time without being discriminated against or retaliated against. My child's medical treatment and rights will not be affected thereby.

As stated in the informed consent form, I agree that the study researchers and other relevant

personnel may access my child's personal data and collect/use such data in accordance with the provisions of this informed consent form. I also agree that my child's personal data may be shared with non-medical professionals. The researcher may terminate my child's participation in this clinical trial if my child requires other diagnosis/treatment, fails to comply with the study plan, or for other reasonable reasons.

Subject's Name: _____

Guardian's Full Name (in block letters): _____

Contact Phone Number: _____

Guardian's Signature: _____ Date: _____ / _____ / _____

Relationship with the Subject: _____

Impartial Witness's Statement

I confirm that the research doctor has accurately explained the information in this informed consent form and other written materials to the guardian. The guardian has clearly understood the information and provided consent voluntarily.

Impartial Witness's Full Name (in block letters): _____

Contact Phone Number: _____

Impartial Witness's Signature: _____ Date: _____ / _____ / _____

Researcher's Statement

I have accurately informed the guardian of the content of the informed consent form and answered all questions raised by the guardian. The subject voluntarily participates in this clinical trial.

Researcher's Full Name (in block letters): _____

Contact Phone Number: _____

Researcher's Signature: _____ Date: _____ / _____ / _____