Iris Eye Care
1st Floor, Anmol Mansion, Dr Lazarus Road, Charai, Thane West 400601 M: +91 9709708480

Researchers Name:

Dr Nishant Tambe
Ophthalmologist

Chandrashekhar Chawan
Optometrist & Ocularist

Apurva Deshmukh
Optometrist

Informed Consent form for Myopia Management with MyoKiddo Mobile specs / 360 bifocals

This informed Consent form is for male and female who are Myopic or whose parents have history of Myopia in the family from age 5 years and older.

Name of Principal Investigator: Dr Nishant Tambe
Name of Organization: Iris Eye Care
Name of Sponsor: Shekhar Eye Research

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

I am Dr Nishant Tambe Ophthalmologist, conducting this Myopia Research for Shekhar Eye Research
We are doing research on Myopia, which is very common around the world.
I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information, and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.

Purpose of the research

The problem of myopia is now being recognized as significant global public health and socioeconomic issue that will affect billions throughout the world, particularly in Asia and in India. It is estimated that 50% of the world's population will be Myopic by 2050.

As myopia rates are increasing worldwide, it is crucial that we take steps to prevent further progression and manage its potential complications to reduce economic burden on society. Poor vision can lead to limitation in mobility, work and overall poor quality of life and dependence on close family members and society.

Knowing the risk factors of high Myopia can help implement early intervention strategies to reduce sight threatening eye morbidities like early cataract, glaucoma, retinal detachment, myopic foveoschisis, retinochisis, myopic macular degeneration, macular hole with or without retinal detachment, peripheral retinal tears, peripapillary deformation, choroidal/scleral thinning, myopic choroidal neovascularization etc. This vision threatening complications can highly impact on quality of life of society and its productiveness.

Development of Myopia can be attributed to environment, ethnicity and genetics, less outdoor activity and more near work, parental Myopia, use of single vision glasses

Estimated value of public health expenditure in India for financial year 2017 to 2020 was whopping 613.98 billion Indian rupees and it will keep on increasing unless preventive measure are taken.

The reason we are doing this Myopia research is to find if we can influence eyeball elongation and control myopia progression with optical devices like 360 bifocal spectacles.

Type of Research Intervention

This research involves taking measurement of axial length of eyeball, measuring refractive error and corneal curvature. Before and after optical intervention.

Participant selection

We are inviting kids age 5 year to 18 years for this research. With a history of Myopia or who's parents are myopic or has family history of Myopia.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this clinic for Myopia management, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

- *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

Information on MyoKiddo Mobile Specs (360 Bifocal spectacles.)

1) 360 Bifocal spectacles have high plus power with a central hole.

2) This high plus power will create Myopic defocus on peripheral retina to stimulate the braing to stop progression and shrink the eyeball.

3) Eyeball may not shrink but it will reduce the eyeball elongation rate as the stimulus continues till the full growth is reached.
4) This bifocal spectacle with a hole in centre is to be used from 30 minutes per day to 2 hours per day depending on the severity of your Myopia while doing intense close work or on mobile phone, ipad or laptops.
5) While using this spectacle you may feel heaviness in head but it will be relieved in few minutes once you are off the spectacles and stop close work for sometime.

Procedures, Protocol and Description of the Process

Your regular eye check up will be performed at the beginning and your refraction, cornea curvature and axial length of the eyeball will be measure.
You will be asked to wear MyoKiddo Mobile specs and watch mobile phone for 1 hour.
After one hour of close activity on any screen your refraction, cornea curvature and axial leght will be measure.
Aging you will be asked to wear this 360 bifocal and continue seeing at your mobile phone for next one hour. Again refraction, K1K2 and axial length will be measure.
After two hours you will be asked to stop all close work and continue to look far off or at a distance for one hour and same test will be performed to compare all the readings.

Duration
Total duration of this research will be 5 hours continuously, including investigation time.

Side Effects
You may feel disoriented or heaviness in head for sometime during or after the procedure.

Risks
There are no known long term risks associated with this research and protocol.

Benefits
Your rate of progression of Myopia will be reduced or stop in long run if you continue the use of MyoKiddo Mobile Specs (360 bifocal) at home for recommended period every day.

Reimbursements
We will give you Rs 500 to pay for your travel to the clinic. You will not be given any other money or gifts to take part in this research.

- *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be re-imbursed? Do you have any other questions?*

Confidentiality
With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except Shekhar Eye Resreah, MyoKiddo, Chandrashekhar Chawan, Dr Nishant Tambe and his staff. This research may be shared with other ophthalmologist and optometrist during the conference and published papers.

- *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any questions about them?*

Sharing the Results
The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.

Right to Refuse or Withdraw
You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

Alternatives to Participating
If you do not wish to take part in the research, you will be provided with the established standard treatment available at the centre

Who to Contact
If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:
Dr Nishant Tambe,
Chandrashekhar Chawan
Apurva Deshmukh

- *Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.*

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Name of Parent / Guardian_____

Signature of Parent / Guardian _____

Date _____
Day/month/year

Statement by the researcher/person taking consent
I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:
1. Eye check up
2. Refraction and Keratometry
3.Axial length measurements

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year