PARENT/GUARDIAN INFORMATION SHEET AND INFORMED CONSENT FORM

Study Title:	MiSight Analysis of Progression (MAP) Study
Protocol #:	MIST-403
Sponsor:	CooperVision Inc.
Study Investigator:	Prof. James Loughman_____.
Study Site Address:	Centre for Eye Research Ireland, Technological University Dublin___.
Telephone Number:	+353 1 4025413_____
After Office Hours:	+353 1 4378314_____

INVITATION

Your child has been invited to take part in a research study. This form describes the study in order to help you decide if you wish for your child to participate. Before you decide, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully, and ask the study investigator or study staff about anything in this form that you have questions about or do not understand. Do not sign this form unless you are satisfied with the answers to your questions and choose for your child to be part of this study.

Your child's participation would be entirely voluntary and, if you agree for your child to be part of this study, you may withdraw this consent at any time without consequence.

WHAT IS THE PURPOSE OF THIS STUDY?

Your child has myopia (short sightedness). With myopia, the light entering the eye is focused incorrectly or rather focused in front of the retina (a thin layer at back of the eye) making distant objects appear blurred. As a result, in order to see distant objects clearly, your child needs to wear glasses or contact lenses. The glasses and majority of contact lenses improve vision, but they do not prevent the myopia getting worse, which means that myopia may increase. A recent study, however, has shown that specially designed soft contact lenses could slow the progression of this condition in children.

The purpose of this study is to investigate whether new designs of contact lenses would have the same effect in children with different levels of myopia as the slowing of myopia contact lens (MiSight®) which is already approved for commercial use in your country. To determine this, the study will be split into two parts: Part 1 and Part 2.

In Part 1 of the study your child would be assigned to the already approved MiSight® lenses, which are designed for myopia control.

In Part 2 of the study your child will be randomly assigned to one of three lens types, all of which are designed to slow myopia progression. Two of the three lens types will be investigational products, and are not yet approved for commercial use, and are not available for sale.

There will be approximately 320 participants across approximately 6 sites worldwide taking part in this study.

WHO CAN TAKE PART IN THE STUDY?

The participants involved in this study will be 7 – 11 years of age (inclusive), currently wearing spectacles or contact lenses and selected on the basis of having healthy eyes, except for the need for vision correction.

The study investigator will check the following to confirm if your child can be in the study:

- If your child's prescription is within the required criteria of the study.
- You are willing for your child to wear the study contact lenses for the required wearing times of at least 10 hours per day for 6 days per week.
- You are willing to bring your child to the study site listed on the first page for study visits. The study visit schedule is listed in another section of this document.
- Based on your knowledge your child has good general health.

Your child should **not be** in this study if any of the following apply to them (the study investigator will review this with you):

- Are using or have used any treatment to slow myopia progression in the past for example atropine or orthokeratology lenses.
- Are wearing or have worn rigid gas permeable contact lenses (for 1 Month or more).
- Have or have had any of the following conditions / diseases:
    - Keratoconus (a cone shaped cornea) or an irregularly shaped cornea.
    - Strabismus (turned or "lazy" eye).
    - Binocular Vision abnormality (difficulty maintaining visual focus on an object with both eyes)
- Have a known allergy to fluorescein, benoxinate, proparacaine or tropicamide.
- Is using any medications that may affect contact lens wear or your child's eyes.
- Has any eye conditions that could affect the eye or mean your child cannot wear contact lenses.

It is important to tell the study investigator about all medication your child is taking, whether obtained by prescription from doctor or bought 'over-the-counter' at a pharmacy.

DOES MY CHILD HAVE TO PARTICIPATE?

No, it is up to you and your child to decide whether or not to participate. You will be given time to consider whether you want your child to take part in this study after reading this Information sheet. Your child will also be given an Assent sheet which explains the study to them. If you agree for your child to take part you will be given this Parent/Guardian Information Sheet and Informed Consent Form to keep. You will be asked to sign the accompanying Consent Form once you have had the opportunity to read all of the instructions and information provided, and received satisfactory answers to any questions you may have. Your child will also be asked to sign the end of the assent form if he/she want to take part. If you and your child agree to participate you/your child are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care your child receives.

WHAT WILL HAPPEN TO MY CHILD FOLLOWING AGREEMENT TO TAKE PART?

The study is designed to be approximately 36 months long. Your child will need to attend eleven scheduled study visits. A study visit is when your child visits the study site at the address indicated on the top of page 1 of this Parent/Guardian Information Sheet. Your child may be asked to attend additional unscheduled visits if necessary. The length of the scheduled visits will vary from 1 hour to 3 hours (as shown below).

VISIT NO.	VISIT	APPROXIMATE VISIT DURATION
PART 1		
1a	Baseline	3 Hours
1b	Trial Lens Fit, Dispensing Part 1 lenses and contact lens Insertion and Removal training	1.5 Hours
2	2-week follow-up	1 Hour
3	3-month follow-up	1 Hour
4	6-month follow-up	1.5 Hours
5	12-month follow-up & Dispensing Part 2 lenses	2.5 Hours
PART 2		
6	2-week follow-up	1 Hour
7	6-month follow-up	1.5 Hours
8	12-month follow-up	2.5 Hours
9	18-month follow-up	1.5 Hours
10	24-month follow-up & Exit	2 Hours

The investigators will perform the 'Visit 1a' examinations after you and your child agreed and signed the relevant documents as mentioned in the above section

In Part 1 of the study all participants will wear the same lens type – the MiSight® lens.

For Part 2 of the study your child will be assigned by chance to one of 3 groups to wear one of the three different types of contact lenses (2 test lens types or MiSight® lens) for the duration of the study. You, your child nor the study investigator will know to which of the lens types your child will have been assigned. All of the lenses, including the control lens are designed to slow myopia progression.

Visit 1a -Screening/Baseline Visit

Your child's full ocular (eye) health will be monitored throughout the entirety of the study (and after where necessary). Your child will have an initial examination of their eyes, and you will be asked questions about your child's general health, contact lens use history and their general outdoor and indoor activities

Many of the measurements taken throughout this study will be similar to those conducted at a routine check-up visit at an eye care provider, although there may be additional clinical testing procedures performed to understand detailed optics about the eye using cutting edge technology and measure complete eye's focussing error. Also, imaging of fine details of the back of part of the eye (retina) may be collected. These measurements will be conducted again at a subsequent relevant study visit.

In general, all these tests will include checking that your child sees well with the contact lenses or spectacles/glasses, that their prescription is correct, and that the lenses fit their eyes well.

Some of the assessments will include, for example, the focusing error of the eye (eye glasses and contact lens prescription), the shape of the front surface of the eye, the alignment of the eyes, how well the two eyes work together, whether one eye is working better than the other, focusing ability for near objects and pupil size. Your child will be shown several letter charts and asked about what they can see to test their ability to see fine detail, and their eyes might be photographed. These pictures will not include identifiable features. Your child's identity will not be disclosed in any photographs. Your child's

eye health at the front part of the eye will be examined with a slit lamp (a light in the shape of a slit and a microscope). Your child will have drops put in their eyes which will dilate the pupils (make the pupils bigger) and allow more area for the light to enter the eyes. Some of the vision measurements will be repeated after the drops have been added (focusing error, focusing ability and eye length) and your child's eye health at the back part of the eye will be examined. The drops will take 30 minutes to work and your child's pupils will return to normal size after approximately 24 hours. Your child will have difficulty reading things up close for a few hours after having their eyes dilated and their far away vision with their glasses may also be a little blurry. For these reasons, do not plan any activities involving reading or being outdoors right after the eye exam, and you should make sure sunglasses and a hat are brought to each visit as your child will be more sensitive to light.

If your child is eligible to participate in this study you and your child will return for the lens fitting visit (1b).

Visit 1b -Trial Lens Fit, Dispensing Part 1 lenses and I&R training

The main purpose of this visit is to fit the study lenses and that you, and your child, become familiar with inserting and removing the contact lenses.

For Part 1 of this study, all participants will be assigned to wear the approved myopia control lens MiSight.

An appropriate pair of contact lenses will be placed on your child's eyes and will be allowed to settle.

The study investigator will then make sure that the contact lenses are suitable for your child by examining them with the slit lamp, ensuring that the contact lenses 'feel comfortable', that your child sees well with the contact lenses, that the contact lens prescription is correct, and that the lenses fit their eyes well. The lenses will correct your child's vision as normal, and your child will wear the same type of lenses in both eyes.

If the investigator is confident that you and your child can insert and remove the lenses, at the end of this visit you will be provided with enough pairs of lenses to last until the next visit. You will also be given additional spare lenses in case they are torn or lost or need to be replaced (for example after swimming). In the meantime, you need to make sure that your child wears the study contact lenses according to the investigator's instructions. The study staff will provide you with written instructions on how to take care of the contact lenses. Should any problems regarding the use of the lenses occur or if you or your child notice any problems with their eyes or vision during the study, your child must stop using the study contact lenses and you must inform the investigator immediately. You may need to come in for an unscheduled visit to check on any potential problems. Additional visits may be required, to properly follow-up on any problems until the problem is fully resolved. Your child taking part in this study must be the only one wearing the contact lenses.

Visits 2-10: Follow-up visits and Exit visit

(2-weeks, 3-, 6-, 12-, 18-, 24-, 30- and 36-months after the dispensing visit)

Your child will be asked to wear the study contact lenses on a daily disposable basis (i.e. for less than 24 hours in a row while awake) for minimum of 10 hours per day and for at least 6 days per week. You and your child will return for check-up appointments as scheduled and your child should wear lenses to the visit.

A Questionnaire is to be completed to evaluate the performance of the study lenses. You and your child will be asked about your experience with the study contact lenses (how you like them, if you have had any problems with them, etc.).

Your child's eyes will also be examined and the assessments completed at visit 1a and 1b will be repeated. Not all the assessments will be repeated at all visits.

For Part 2 of this study at 12-months Follow up visit, all participants will be assigned by random chance to wear one of 3 treatment groups to wear one of the different types of test contact lenses for the duration of the study.

Study visits are essential in order to collect data about the study lenses and to ensure continued ocular (eye) health; therefore, you must follow the visit schedule as instructed by the investigator. These study visits do not replace your regular periodic eye examinations, which you should carry on attending.

If your child has any problems using the study contact lenses, or has any problems with their eyes during the study, your child should stop using the contact lenses and you should contact the site or other eye care professional. In the case of an emergency you should attend with your child your nearest Accident and Emergency department and inform them your child is participating in a contact lens clinical trial.

As part of the study the researchers would like a saliva sample to be taken from your child at the Part 1, 6-month follow up visit. This is voluntary and your child can still take part in the study if you decide not to agree, however it will help the study research if you agree. The researchers are trying to investigate whether there may be a genetic link to how children responded to myopia control treatment.

The goals of this genetic study are to better understand how genetics influences response to myopia treatment. Your child's DNA will be tested to look for genetic changes that may cause a better (or perhaps a worse) response to myopia therapy. No other genetic changes or genetic disorders in your child will be looked at during this study. Participation in this study may not help your child's own myopia treatment, but may assist with the treatment of other children in the future.

If you agree for your child to undergo this optional procedure, then a small amount of your child's saliva will be collected in a pot specifically for saliva collection. It will not be painful and will only take a few minutes to collect. The saliva will be evaluated for information regarding this study and therefore you will not be notified about the results.

Biological samples (the saliva) collected from your child will be anonymised, and will be the only samples (along with the related data) to be transferred out of this country Professor Mark Willcox at School of Optometry and Vision Science, University of New South Wales, Sydney, NSW 2052, Australia. The saliva samples obtained during this research procedure will be used only for this research, and will be destroyed when the research is completed.

Any other information containing your child's "Personal Data", and any such information that is collected or generated for the purposed described in this Informed Consent Form will be stored in this country.

At the end of each visit, you will be provided with enough pairs of lenses for your child to last them until the next scheduled visit.

When you and your child return for each scheduled visit you will be asked to bring any unworn lenses with you in case your child needs a different prescription. Lenses that have been worn throughout the study should be disposed of at the end of each day, and do not need to be saved for return to the Investigator.

If your child fails to adapt to the lenses in part 2 of the study or if wants to discontinue from the assigned lenses, you will be given the option for your child to be refit back to previously assigned lenses and continue in the study.

WHAT WILL I AND MY CHILD HAVE TO DO?

During the study you and your child must:

- Follow the instructions you are given.
- Keep your study visit appointments. If it is necessary to miss an appointment, please contact the study staff to reschedule as soon as you know you will miss the appointment.
- Tell the study staff about any changes in your child's health.
- Keep the study contact lenses in a safe place and for your child's use only.

- Tell the investigator about all medications your child is taking, whether obtained by prescription from doctor or bought 'over-the-counter' at a pharmacy.
- Tell the study staff if you/your child want/wish to stop being in the study at any time.

The lenses being used in this study are daily disposable. This means that your child will need to remove them and throw them away every night, and replace them with a new pair in the morning. Your child must not sleep in the study contact lenses at any time. Do not allow the lenses to come into contact with water. If your child wishes to swim, they should not wear their contact lenses while swimming. Before swimming your child should remove the contact lenses from their eyes and throw them away. After swimming your child should put a new pair of contact lenses on their eyes, or wear their glasses for the rest of the day.

During the study, when study contact lenses are not worn either glasses must be worn or no vision correction. Your child must not wear any other type of contact lenses during the study.

Unscheduled visits will be made available to your child, at your request or if the investigator thinks it is in your child's best interests.

At the end of your child's participation in the study you are required to return all study products that have been issued for your child.

IS THERE ANYTHING ELSE I CAN DO FOR MY CHILD'S EYESIGHT?

Your child should continue to go to their regular eye care practitioner even if they participate in this study.

Your child does not have to be in this study to get help for their eyesight. The study investigator will talk to you about other things you can do for your child's eyesight. Some other things your child can do are:

- wear spectacles
- use approved soft or hard contact lenses
- get laser or other refractive surgery
- have no vision correction

You can talk to your child's primary eye care provider about your options.

WHAT ARE THE SIDE EFFECTS OF ANY TREATMENTS MY CHILD MIGHT RECEIVE WHILST TAKING PART IN THE STUDY?

Your child could potentially experience the side effects of contact lens wear, which include excessive watering of the eyes, unusual eye secretions, or redness of their eye(s). Occasionally poor visual acuity (lack of ability to see fine detail), blurred vision, rainbows or halos around objects, photophobia (light sensitivity), or dry eyes may also occur. If your child experiences any eye discomfort, excessive tearing (this refers to your eyes producing an abnormal amount of tears), sudden vision problems or changes, redness of the eye, or other problems, your child must immediately remove their contact lenses and you must promptly contact the investigator listed on the front page of this document.

The side effects of the dilation drops are the same as dilating eyes during a standard exam. Possible side effects of dilation eye drops are: stinging, increased pressure inside the eyeball, redness of the eye and rarely, facial flush (redness and warmth) and nervous system disturbances (such as disorientation or feeling tired).

It is possible that there are other side effects from the lenses or procedures that no one knows about. If any additional side effects are identified during the study you will be notified so you and your child can make a decision on whether to continue participation in the study.

In an emergency, if you are unable to reach the investigator please remove your child's lenses and go to your nearest hospital emergency department. Inform the attending staff of your participation in the study.

WHAT ARE THE POSSIBLE DISADVANTAGES (RISKS) FOR MY CHILD OF TAKING PART IN THE STUDY?

Problems with contact lenses or lens care products can result in serious injury to the eye. These complications can include light sensitivity, swelling of the cornea (the front part of the eye), red eye, corneal vascularisation (small blood vessels growing into the cornea) and, in extreme cases, corneal infection. If serious, these complications can lead to permanent loss of vision. If a complication should occur during the study your child's eyes may be photographed. These pictures will not include identifiable features. Your child's identity will not be disclosed in any photographs. A longer appointment may be necessary and your child may be referred for medical treatment. Your child may be required to wear spectacles for a period of time.

All side effects and risks of contact lens wear can be reduced by making sure your child does not sleep while wearing the contact lenses, and by ensuring all the instructions given by the investigator for lens wear are followed by your child.

WHAT ARE THE POSSIBLE BENEFITS FOR MY CHILD OF TAKING PART IN THE STUDY?

The expected benefits of contact lens use in general include improved vision (compared to not wearing any vision correction), comfort, convenience, and cosmetic advantage. We hope that all treatments benefit participants, although this cannot be guaranteed. Children wearing contact lenses may benefit from contact lens wear due to the quality of life improvements associated with wearing contact lenses instead of eye glasses to correct their vision. Contact lens wear has been found to improve how children feel about their appearance, athletic competence and social acceptance. Information from this study may help researchers to develop better contact lenses able to slow down increases in myopia.

Results from this study will also help researchers to better inform eyecare practitioners and the general public regarding the treatment of near-sightedness with MiSight lenses and other test lenses.

Recent studies, have shown that specially designed soft contact lenses could slow the progression of myopia in children, however we can't guarantee that will happen in this study.

WILL IT COST MY CHILD ANYTHING TO PARTICIPATE?

There is no cost to you or your child for study procedures or products.

Will I or my child receive any compensation for participation in this study?

Reasonable travel and participation will be reimbursed to you on production of relevant receipts.

The investigator can tell you more about how and when you will receive this compensation.

WHAT IF NEW INFORMATION BECOMES AVAILABLE?

Sometimes during the course of a research project, new information becomes available about the product that is being studied. If this happens, your Investigator will tell you about it as soon as possible and discuss with you whether you wish for your child to continue in the study. If you wish to discontinue your child's participation, your Investigator will make arrangements for your child's eye care to continue or you should consult the regular optometrist of your child. If you decide for your child to continue in the study you and your child will be asked to sign updated Consent and Assent forms.

Furthermore, on receiving new information your Investigator might consider it to be in your child's best interests to withdraw your child from the study. The Investigator will explain the reasons and arrange for your child's eye care to continue or you should consult your child's regular optometrist. If you wish for your child to stop participating before the end of this study then the data collected up to the withdrawal may be useful and may still be used in analysis. Please inform the investigator if you do not want data collected for your child to be used.

WHAT HAPPENS TO MY CHILD WHEN THE RESEARCH STUDY IS OVER?

After the study, whether your child successfully completes the study or is discontinued from the study for any reason, your child's regular optometrist will be able to advise you of appropriate contact lens products or other vision correction products for your child.

If the sponsor decides to stop the study prematurely, the reasons will be explained to you and your child.

WHAT IF MY CHILD GETS HURT OR SICK WHILE THEY ARE IN THE STUDY?

If your child gets hurt or sick while participating in this study, and the study investigator and the study sponsor reasonably determine your child's illness or injury to be a direct result of the study medical treatment will be provided by the sponsor. If your child has not followed the study investigator's instructions about the study, the sponsor may not pay these expenses.

The sponsor has made arrangements for insurance and / or indemnity to meet the potential legal liability of the sponsor arising from the study. You / your child will not lose any legal rights by participating in this study.

To ask questions about this, talk to the study investigator or study staff.

WHO IS FUNDING THE STUDY?

CooperVision Inc. USA is sponsoring this study. As well as reimbursing your costs, the sponsor will pay the study investigator for their time, effort and expense to conduct this study.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results of the study may be published, used in advertising or sent to the appropriate health authorities in any country in which the product may ultimately be marketed, but yours or your child's name will not be disclosed in these documents. If participants are interested in obtaining the results of the study, they should contact Visioncare Research at the end of the study.

In addition, 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 or your child. At most, the web site will include a summary of the results. You can search this web site at any time.

WHO HAS REVIEWED THE STUDY?

This study has been reviewed and approved by an ethics committee responsible for scientific integrity and patient wellbeing. This study has also been approved by your country's Regulatory Authority responsible for the legal and scientific accuracy of clinical trials.

CONTACT FOR FURTHER INFORMATION

If you have any questions about the study please contact the Investigator using the telephone number on the front of this document.

If you require further information or have other questions you can also contact Visioncare Research on the following email address: research@visioncare.co.uk

For questions about rights and safety as a study patient, please contact Prof. James Loughman at +353 1 4025413

You will be given a copy of this Participant Information Sheet and signed Informed Consent Form to keep.

HOW WILL MY CHILD'S PERSONAL INFORMATION BE USED AND IN WHICH CASES WILL IT BE SHARED?

If your child participates in this study, the study investigator/staff will collect and use your child's personal data as needed to conduct the research study described above. This personal data will include your child's name, address, date of birth, and information about your child's health. Sensitive data such as race / ethnic origin and gender may also be collected, as it is necessary for the evaluation of the study results. Your child's participation in the study will be kept confidential within the study team and those with access to your child's personal information.

We are collecting and storing this personal information in accordance with the General Data Protection Regulation (GDPR) and Data Protection Act 2018 which is legislation designed to protect your and your child's personal information.

The legal basis for the processing of personal data is "public interest task" and "for research purposes".

Your child's encoded personal health information and all other data collected during the study visits will be entered by the investigator, Sponsor or representatives of the Sponsor onto a database which is managed by a company called Medrio. Medrio, the Sponsor, Visioncare Research and other Sponsor representative personnel who are working on the study will have access to the data in this database. Medrio is a US company and therefore any data entered in the database is transferred to the US. The European Union and the United States take different approaches to privacy of data and US laws may not be as strict as the EU laws. In order to bridge these differences in approach, Medrio will ensure any transfer of data to them are handled in accordance to the EU directives on data protection as set out in Privacy Shield. You can find out more about Privacy Shield by visiting the following website: Privacy Shield - https://www.privacyshield.gov/.

The data controller for the personal data at this study site is the Principal Investigator. If you have questions about this, talk to the study investigator or study staff.

Who will have access to your child's personal data?

Your child's personal data will be stored in limited-access paper files and/or electronic databases. The study investigator / staff will have access to these paper files and databases. Other people may also need to see this information to ensure that the research study is being conducted properly, in accordance with laws and ethical requirements, including:

- People authorised by the sponsor such as monitors and auditors;
- The independent ethics committee that reviews the study to ensure that it meets scientific and ethical standards;
- People from regulatory authorities overseeing the study (such as the MHRA in the UK).

How will your / your child's personal data be protected?

As a study participant your child will be assigned a study identification number. Any personal data that leaves the investigator's clinic (study site) will be labelled with this ID number (encoded data), meaning your child's data will be anonymised. No personal identifiers such as name, initials or address will leave the investigator's clinic.

The data controller for your child's encoded data is Technological University Dublin

How will your child's coded data be shared and transferred?

Representatives of the sponsor (for example; study monitors and auditors) may use an electronic tool to access your child's encoded data remotely. This electronic tool provides a secure gateway between the study site's computer system and the computer of the sponsor's representatives.

Your child's coded data may be used for submissions to regulatory authorities, to help with the design of future studies and for research which is compatible with investigations related to this study including statistical purposes.

This information will not identify your child to any external personnel and will not be combined with other information in a way that could identify your child. The information will only be used for the purpose of health and care research, and cannot be used to contact you / your child regarding any other matter or to affect your child's care.

How long will my child personal data be stored?

Information by which you / your child can be identified will be kept in accordance with research regulations. The research site is required to keep Consent and Assent forms and participant's records which contain personal information for a number of years after the research has been completed which is in accordance with national legislation. All essential study documents will be retained for at least 2 years after formal discontinuation of clinical development of the investigational product. In addition, the sponsor will retain your child's coded data for a period as allowed per applicable laws for the identified use.

What rights do I and my child have concerning our personal data?

You / your child have a number of rights under data protection law regarding your / your child's personal information. For example, you can request a copy of the information we hold about your child, including photographs. This is known as a Subject Access Request. If you would like to know more about your child's different rights, please contact Prof. James Loughman at +353 1 4025413.

You may request your information by email through foi@tudublin.ie and may also contact the Information Governance Officer at Technological university Dublin at:

The Information Governance Officer, City Campus

TU Dublin –Park House 191 North Circular Road Grangegorman, D07EWV4, Ireland

Study Number: MIST-403

CONSENT FORM

Version 1, dated 11 November 2019

Study Title: MiSight® Analysis of Progression (MAP) Study

1. I confirm that I have read and understand all pages of this information sheet for the above study and have had the opportunity to ask questions. Any questions I had were answered to my satisfaction.	☐
2. I understand that my child's participation is voluntary and that I and my child are free to withdraw at any time, without giving any reason, and without our future care or legal rights being affected. I understand that any data collected up to the time of my child's withdrawal can still be used in the study.	☐
3. I understand that my child's eye clinic notes and research data may be looked at by responsible individuals from the sponsor company, Visioncare Research or from regulatory authorities where it is relevant for my child taking part in this research.	☐
4. I agree to the sponsor company or Visioncare Research Ltd processing my and my child's personal data, which I have supplied, and I understand that our pseudonymised data will be sent to the sponsor company. I agree to the processing of such data for any purposes connected with the research study as outlined to me. I further agree to the sponsor company or Visioncare Research Ltd processing personal data about my child described as sensitive data within the meaning of the Data Protection Act 2018 and GDPR.	☐
5. I understand that my child's pseudonymised data will be exported outside of my country to the sponsor company in the US: CooperVision Inc.	☐
6. I agree to my child's anonymised data being used by research teams for future research.	☐
7. I agree to mine and my child's personal data being processed for the purposes of inviting me or my child to participate in future research projects. I understand that I may opt out of receiving these invitations at any time.	☐
8. I agree for my child to take part in the above study.	☐

The study Investigator has my permission to tell my Medical Doctor about my child being in this study: YES ☐ NO ☐

The study Investigator has my permission take a sample saliva sample from my child: YES ☐ NO ☐

_____	_____	_____
Name of Parent/Guardian	Date	Signature

I confirm that I discussed this study with the above-named Parent/Guardian. This person had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed for their child to participate in this study.

_____	_____	_____
Name of person taking consent	Date	Signature

_____	_____	_____
Name of Investigator	Date	Signature

OR ☐ N/A If Investigator is person explaining consent

Patient Identification Number for this trial: ____ / ____ (if applicable)