

Parents/Guardian of:

Normal Eye Growth in Children Research Project

Patient Information Sheet

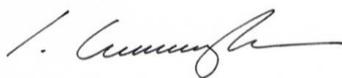
We would like to invite you and your child to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. We are recruiting children for this study that are undertaking a surgical procedure unrelated to an eye condition.

On the day of the operation one of our research team will go through this information sheet with you and answer any questions you have.

We'd suggest this should take about 5 minutes. If you wish, you may talk to others about the study or contact a member of the research team directly.

Please ask us if there is anything that is not clear. Frequently asked questions have been summarised on our co-funders website which is available at www.vision4children.org.uk under the research section.

Thank you for reading this.



Mr. Ian Cunningham
Research Optometrist
Ophthalmologist



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Consultant

Normal Eye Growth in Children

Patient information.

Version 2: June 2009

What is the purpose of the study?

When a child is born with cataract, severe loss of vision results unless it is removed. Following removal of the cataract an artificial lens (IOL) is usually implanted within the eye to focus images on the retina (the eye's refraction). It is the power of the IOL, the resultant clarity of the image on the retina and the subsequent manipulation of this, which, then determines the future visual development of the child. Choice of the power of the IOL is of paramount importance and there is currently no accurate method for estimating the result that you will get from the choice of IOL strength.

In our department at Alder Hey – we are aiming to solve these problems once-and-for-all and we need your help.

In medicine, before we treat any abnormalities we have to know the normal values. In the case of childhood cataract we need to know how a normal child's eye develops and that is why you have been approached as being part of our study.

Why have we been invited?

Because your child has normal eyes.

Do we have to take part?

Absolutely not. It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to my child if I take part?

We are examining the eyes of children that are undergoing a surgical procedure. We propose to perform the measurements just after your child has been sedated and before their operation. It is a very simple examination that adults and older children undergo in our eye clinic whilst awake.

The examination is split into 3 parts:

1. An ultrasound examination to measure the length of the eye and its structures.
2. A light test to measure the shape of the eye
3. A pressure test – much like the 'airpuff' test you may have experienced at the opticians.

The ultrasound examination is done via a small probe that is balanced on the eye and sound waves pass into the eye and bounce back to the probe. This is exactly the same principal as the ultrasound examination performed in pregnant ladies.

The light test involves light (that is not visible to the human eye) being shone onto the eye and a measurement of how it is reflected. All tests are completely routine in the eye clinic. There is no dangerous radiation from either aspect of the test.

These tests will not affect the treatment of your child in either a positive or negative way – i.e. having it does not make the treatment any more (or less) effective – we will not interfere (or even be present) for your child's main operation. The results of this research will enhance our knowledge for the future and aid the treatment of others.

All information collected about your child will be kept strictly confidential. The only details that are recorded will be:

1. Age
2. Gender
3. Height
4. Weight
5. Eye Measurements

These measurements will then be collated on a database and when we've enough measurements then we will know how the normal eye develops.

What will we have to do after the procedure, if we take part?

Nothing. It is a single set of measurements. We will not contact you again unless your child happens to undergo a further operation within the study period, when you may be asked to participate again!

What are the benefits of taking part?

The study will not directly help you or your child but the information we get from the study will help countless children born with cataract.

Will my taking part in the study be kept strictly confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence

What if something goes wrong?

It is extremely unlikely that these measurements will cause any degree of harm. There is a theoretical risk of scratching the front surface of the eye (the cornea) but this will heal itself within 24 hours. If your child is harmed by taking part in this research project due to someone's negligence, then you have grounds for a legal action but you may have to pay for it.

Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaint mechanisms should be available to you.

Will my GP be informed?

No – only in the extremely unlikely event that there is a problem

Will any samples be collected?

Absolutely not. We are only measuring different parts of your child's eyes.

Thank you for considering to be entered into our study.

If you have any queries regarding this please contact:

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