# Cataract and natural lens replacement (NLR) surgery Informed consent document

surgeon or an independent practitioner at the end of this

I am aware of the facts stated above.

Write your initials here:

This document is a legal document. You need to sign it to give the surgeon your written permission to treat you. It is important that you bring this document with you on the day of your treatment. If you do not understand anything in this document, please ask us for more information.

| treatment. If you do not understand anything in this document, please ask us for more information.  |  |
|---|--|
| Patient's name:   | Patient's central ID:  |
| Eye to be treated: Right eye Left eye   |  |
| Informed consent  |  |
| Background information  | I understand that my surgeon may decide to change the  |
| We aim to tell you all about the risks, benefits and alternative treatment options of cataract and natural lens replacement (NLR) surgery.  | type of procedure I have if a different surgical approach would be safer or would provide a better outcome.  |
| It is important for you to understand that there are risks with   | Write your initials here:  |
| any type of surgery. This informed consent document, along with the information you received at your pre-treatment consultation, is designed to make sure that you can fully  | Before your treatment you must tell your surgeon if any of the following applies.  |
| consider the risks and benefits of the surgery you have been scheduled for and make an informed decision on whether or not to go ahead with the treatment.  | <ul> <li>You have any eye problems, including amblyopia (lazy<br/>eye), strabismus (muscle imbalance which can cause<br/>double vision), severe dry eyes or any recurrent (keeps<br/>coming back), residual (an after-effect of another</li> </ul> |
| We are giving you all this information before your treatment<br>so that you have enough time to consider all aspects of   | condition) or active eye conditions.   |
| your treatment before your surgery.  The information in this document applies to all types of   | <ul> <li>You are a carrier of methicillin-resistant staphylococcus<br/>aureus (MRSA) or have been exposed to MRSA.</li> </ul>  |
| cataract and NLR surgery.   | <ul> <li>You have any general health conditions, including back<br/>problems or claustrophobia or other psychological<br/>conditions (including a history of anxiety or depression).</li> </ul>  |
| Please initial each point below to confirm that you understand the information.   | <ul> <li>You have any implants, including a cardiac pacemaker,<br/>insulin implant or other electronic implanted device.</li> </ul>  |
| Management of the state of the | • You are allergic to any medications or latex.  |
| Your surgeon will decide whether you are suitable for treatment after carrying out a careful examination, discussing the treatment with you and considering your optometrist's opinion. The surgeon's decision will be based on your individual needs.  | <ul> <li>You are taking or using any medications, eye drops<br/>or supplements, including vitamins or nutritional<br/>supplements you have bought 'over the counter' without<br/>a prescription.</li> </ul>  |
| Please tell your GP that you are considering cataract or NLR surgery, as they can give you independent medical advice.  | <ul> <li>Your current or planned occupation prevents you from<br/>having a multifocal lens implant, any type of lens surgery<br/>or laser eye surgery.</li> </ul>  |
| If you have any questions about your treatment, you should ask your surgeon before you sign this document.  | <ul> <li>You have had an eye injury or eye surgery in the past.</li> </ul>   |
| The purpose of this part of the document is to confirm that you have understood all of the information you have received  | <ul> <li>You are pregnant, breastfeeding or could possibly be<br/>pregnant.</li> </ul>   |
| and to keep a record of your decision to go ahead with the treatment.   | It is vital that you have fully and accurately filled in the health questionnaire you received at your pre-treatment consultation before you meet your surgeon for treatment.  |
| I have read and understood the points discussed in this section.  | The information in this document is extremely important as   |
| Write your initials here:   | it will help your surgeon to decide whether you are suitable for the treatment.  |
| I understand that my surgeon will be registered with  | I have read and understood this section and have met all the conditions.   |
| the General Medical Council. I understand I should visit www.gmc-uk.org for the benefits this offers me. I also understand my surgeon may be an independent   | Write your initials here:  |
| practitioner using facilities you have provided.  | General information  |
| You will tell me whether my surgeon is an Optical Express   | There are two types of surgical procedures described in this   |

Page 1

document. Both procedures involve removing the natural lens of the eye and replacing it with an artificial lens implant.

These procedures are basically the same. However, the reasons for carrying out each procedure are different. These

are described below.

#### The cataract surgery procedure

Cataracts develop when the natural lens inside your eye becomes cloudy, making it difficult for you to see well enough to carry out your usual daily activities. A cataract cannot be corrected with medications, glasses, contact lenses or laser eye surgery. The purpose of this procedure is to replace the cloudy lens (cataract) with a clear lens implant inside your eye to restore your vision that you have lost due to the cataract. Another benefit of this procedure is that it could reduce your need for glasses or contact lenses, if you previously needed these.

The natural lens replacement (NLR) procedure

NLR is a procedure to correct vision. Patients can choose to have this treatment if they want to reduce the need to wear glasses or contact lenses. NLR is similar to cataract surgery and corrects vision by replacing the natural lens in the eye with a new lens of the correct focusing power. The procedures involved in cataract and NLR surgery are explained in more detail in the information you received at your pre-treatment consultation.

I understand the above and all of my questions have been answered.

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### All-laser (femtosecond) surgery

Femtosecond lasers can now be used in cataract and NLR surgery, and their role is to help with or replace several parts of the manual cataract or NLR surgery.

For many years femtosecond lasers have been successfully used in LASIK surgery.

Traditionally, the surgeon uses a surgical blade to make the incisions in the front window of the eye known as the cornea, and uses other special instruments to make the circular incision in the outer layer of the cataract or clear lens. This procedure is known as a 'capsulotomy'. The surgeon then uses a high-powered ultrasound phacoemulsification device to break up the natural lens and remove it from the eye. The femtosecond laser can be used to carry out some or all of these steps. The possible benefits of using the laser include the ability to make more precise and consistent incisions in the cornea, a more circular and centred capsulotomy, and to soften the cataract before it is removed so less ultrasound energy is needed with the phacoemulsification device. It is also possible to make accurate incisions in the cornea (known as 'astigmatic keratotomy' or AK) to reduce astigmatism. The laser will help the surgeon make the surgery safer and easier for you. In turn, this aims to improve clinical outcomes.

I have read and understood the points discussed in this section.

| Write your initials here: |  |
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Using the laser does not take away the risk of complications during or after surgery, which include decentration of the corneal or capsulotomy incisions, incomplete or interrupted capsulotomy, fragmentation, or corneal incision procedure, anterior capsular tear, posterior capsular tear with lens or lens-fragment dislocation into the vitreous, corneal abrasion or defect, pain, infection, bleeding, damage to intraocular structures, fluid leaking from the anterior chamber, collapse of the anterior chamber, and increased eye pressure. (Your refractive optometrist or surgeon will be able to provide more information on these conditions.)

In the case of an interrupted or incomplete corneal incision, the incisions can be made using hand-held blades. In the case of an incomplete or interrupted capsulotomy, the procedure can be completed using traditional manual capsulotomy methods. In the case of an incomplete or interrupted

fragmentation, the procedure can be completed or repeated using conventional phacoemulsification treatment. In the case of loss of lens fragments into the vitreous, a separate procedure called a vitrectomy may be necessary to remove the vitreous gel and lens fragments.

Most people treated with the laser report temporary small, red spots on the sclera (the white of the eye) after treatment. These spots are called 'petechiae' and are caused by small blood vessels that break due to the suction cup that is placed on the eye during laser treatment. The suction cup is used to keep the eye still during the laser treatment.

In some people, the red spots covered a larger area of the sclera, and this is called a 'subconjunctival haemorrhage'. The people who reported these effects also reported that the effects usually went away within seven days.

I have read and understood the points discussed in this section.

| Write your initials here: |  |
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Just before surgery, we may give you a sedative to help you relax. We will also give you a local anaesthetic to numb the eye, and we may give you eye drops to dilate the pupil. During surgery you will be in a comfortable lying position. You will need to lie as still as possible.

You will be awake and be aware of a bright light, but you will not be able to see what is happening. Cataract and NLR surgery takes around 20 minutes. The natural lens is removed through a tiny incision using gentle ultrasonic waves. An artificial lens is then inserted into the space where the natural lens used to be. The incisions are made with the intention that they will seal on their own, but occasionally one or two stitches may be needed. If you need stitches, we will do these under local anaesthetic. The stitching procedure is painless and takes about 20 minutes in total. We will give you antibiotic eye drops to reduce the risk of infection. After your surgery we will place a protective shield over the eye.

I understand the above and all of my questions have been answered.

| Write your initials here: |
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There is a significant amount of medical evidence which shows that cataract and NLR procedures are safe and effective. However, it is not possible to absolutely guarantee that cataract or NLR surgery will improve your vision or that you will not need other types of treatment to improve your vision.

I understand the above and all of my questions have been answered.

| Write your initials here: |  |
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Although we confirmed that your prescription was stable at the time of your pre-treatment consultation, it is still possible for you to develop further short-sightedness, long-sightedness or astigmatism over time after treatment, even if the treatment is successful in correcting your vision.

I understand the above and all of my questions have been answered.

| Write your initials here: |  |
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Cataract and NLR surgery involves removing the eye's natural lens and inserting an artificial lens implant into the

eye. We decide the power of the new lens as accurately as we reasonably can before the treatment, to reduce or correct short-sightedness, long-sightedness or astigmatism. However, because healing patterns are unpredictable and because of other surgical factors (for example, the exact position the artificial lens settles in after the surgery), we may not achieve the result we are aiming for after one or several treatments, even with the correct lens power. So, even after treatment, you may still need glasses or contact lenses, or need laser eye surgery or further lens replacement surgery, to achieve the best vision possible.

I understand the above and all of my questions have been answered.

Write your initials here:

As part of your lens surgery you can choose to have a monofocal (single focus) lens implant to correct your vision at one distance, typically for far vision, and wear separate glasses for close-up work. The aim of this approach is that you are left with very clear distance vision with both eyes. The disadvantage is that you will need to wear glasses, typically for near vision.

I have read and understand this section. I understand that if I choose monofocal lens implants to correct my vision at one distance, I may need to use glasses after my treatment.

Write your initials here:

When we are young, our eyes can focus at all distances, from very distant objects to very near objects (like an auto-focus camera). This ability to focus weakens throughout life. From about the age of 40, this loss of near focus begins to affect our ability to read and see close-up things clearly. This weakening continues until you are about 60 years old, at which time you have almost no ability to change focus. The loss of ability to focus results in the need for reading glasses, even for people who have previously had excellent distance and near vision without glasses. This process (called 'presbyopia') happens in everyone.

People with presbyopia usually need bifocal, varifocal or separate reading glasses to see clearly at close range. If you are short-sighted, you can compensate for this loss of near focus simply by taking your glasses off or your contact lenses out. If you are short-sighted and choose to have both eyes treated to give you the best distance vision, you will lose the ability to compensate for your loss of near focus.

The most important thing to remember is that if you have presbyopia and choose to have both eyes treated to give you the best distance vision, you will need to wear glasses for most near-vision activities after treatment, not just reading. This includes most close-up tasks, such as using a computer, looking at your mobile phone, applying make-up, reading a menu and so on.

I have read and understand this section. I understand the issues of presbyopia, loss of ability to read and focus, and the need for glasses. I understand that if I have presbyopia and choose to have my distance vision corrected in both eyes, I will need to wear glasses for most near-vision activities after having laser eye surgery.

Write your initials here:

An alternative method of treatment for patients with presbyopia is a technique called 'monovision', where a single-focus lens for best distance vision is implanted in one eye and a single-focus lens for best near vision is implanted

in the other eye. The possible advantage of this technique is that it gives you a better range of vision and reduces the need for glasses.

This combination of a distance eye and a reading eye may allow you to see clearly at both far and near distances without glasses. Monovision has been used successfully for many contact lens wearers and for patients who have had laser eye surgery. Possible disadvantages include reduced overall quality of vision and a reduced ability of both eyes to work together to help with depth of vision (depth perception).

It can also take some time for your eyes to adapt to the new lenses and you may still need glasses for certain tasks. If your eyes do not adapt, it may be necessary for you to have further treatment.

I understand that if I choose to be treated using the 'monovision' technique, my depth perception and overall quality of vision may be reduced and that I still may need glasses for certain tasks. I understand that with the 'monovision' technique my eyes can take time to adapt to the new lenses and I may need further treatment.

Write your initials here:

Multifocal lenses are an advanced form of intraocular lens technology. They can provide excellent distance, intermediate and near vision using multiple optical powers in the same lens. This can improve your near vision and reduce your need to rely on reading glasses, although it is possible that it will not restore all of the ability to focus at near (or intermediate) distances. A possible disadvantage of this type of lens can be glare, shadowing or 'halos' around lights in situations with low lighting such as at night, and this may make driving at night more difficult. If you do have these symptoms following your treatment, you could consider a lens exchange, where the lens is removed and replaced with a different design of lens such as a single-focus lens. This additional treatment will present further surgical risks and will result in a change in your distance vision, intermediate vision and near vision.

You will also need more follow-up appointments after the additional treatment.

I understand the benefits and possible side effects of multifocal lenses and that they may not restore all of the ability to focus at near (or intermediate) distances, and so I may still need glasses for certain tasks.

Write your initials here:

Cataract and NLR surgery will not correct other causes of poor vision such as amblyopia (lazy eye), vitreous opacities (floaters), glaucoma, diabetes, age-related macular degeneration or any other retinal or optic nerve conditions.

I understand the above and all of my questions have been answered.

Write your initials here:

After having cataract or NLR surgery, it is possible that you may develop eye conditions that are unrelated to, and not caused by or prevented by, cataract or NLR surgery, such as glaucoma, age-related macular degeneration and other conditions of the retina.

I understand the above and all of my questions have been answered.

Write your initials here:

#### Alternatives to cataract surgery

Cataract surgery is an elective procedure. This means you can choose whether or not to have it. However, in most cases it is considered a necessary procedure to restore lost vision that cannot be corrected in any other way. There are currently no alternative types of non-surgical or surgical treatments to correct loss of vision caused by cataracts.

I understand that cataract surgery is currently the only effective method for restoring lost vision caused by cataracts. I understand that I can choose not to have cataract surgery, but that currently there are no other effective methods to correct or restore vision that I have lost due to cataracts. I understand that cataract surgery is an elective procedure and that I do not have to have the treatment.

Write your initials here:

## Alternatives to NLR surgery

NLR is an elective procedure. This means you can choose whether or not to have it.

There are other ways to correct your vision, some which involve surgery and some which do not, including glasses, contact lenses, another type of lens surgery and laser eye surgery, which may be able to help with your condition.

You have received this document because we have recommended NLR surgery as the best procedure to meet the goals you have identified during your pre-treatment consultation. However, if you would like more information about other treatment options, please ask us.

I understand that there are alternatives to NLR surgery. I understand that NLR surgery is an elective procedure and that I do not have to have the treatment.

Write your initials here:

# Possible risks, complications and desired results

Due to uncertainties in healing patterns and other aspects of surgery, we may not fully achieve the desired result from the treatment you are scheduled for after a single procedure. So, even after surgery, you could be short-sighted, long-sighted or have astigmatism and may need to wear glasses or contact lenses or have more surgery. Your eyes may also go back towards their original prescription.

Laser enhancement surgery may be possible when your prescription is stable, there is enough corneal tissue available and there are no medical reasons why laser eye surgery could not be safely carried out.

Although laser enhancement surgery is generally very effective, there are extra risks involved, and we cannot guarantee we will achieve the result we are aiming for. Laser enhancement surgery can usually only be considered three to six months after cataract or NLR surgery.

I understand the above and all of my questions have been answered.

Write your initials here:

The results of surgery cannot be guaranteed and you may need further treatment or surgery (or both) to achieve a result you are happy with.

I understand the above and all of my questions have been answered.

Write your initials here:

Following cataract or NLR surgery, there is the risk that you could develop a secondary cataract, also known as 'posterior capsular opacification' (PCO). Although the natural lens is removed during surgery, the capsule surrounding the back of the lens is left intact to support the lens implant. It is possible for the capsule to become cloudy and reduce your vision during the months or even years following your surgery. However, if this happens, vision can usually be successfully and quickly restored using a specialised laser called a YAG laser. This procedure takes only minutes to carry out, is not painful and produces almost immediate improvement in vision.

I understand the above and all of my questions have been answered.

Write your initials here:

Neither cataract nor NLR surgery is reversible (the natural lens cannot be put back in your eye). At some point in the future, due to unforeseeable circumstances, the lens we have implanted may need to be repositioned or replaced with a different design of lens. This applies whichever type of lens is used.

I understand the above and all of my questions have been answered.

Write your initials here:

Night-vision disturbance, such as glare and 'halos', or double vision or seeing 'ghosts' around things, are common immediately after cataract or NLR surgery, but in most cases these symptoms gradually disappear over a period of weeks or months following the treatment. These night-vision symptoms may be more common with multifocal rather than monofocal lens implants. In rare cases, night-vision problems may last for longer or could be permanent.

I understand the above and all of my questions have been answered.

Write your initials here:

You will be given an anaesthetic as part of the cataract or NLR surgery. There are risks associated with the use of anaesthetic, including a squint or 'lazy eye', droopy eyelids, enlarged pupils, partial or complete blindness, and cardiac and respiratory problems.

I understand the above and all of my questions have been answered.

Write your initials here:

In rare cases, cataract or NLR surgery can lead to an infection within the eye (endophthalmitis) or on the outer surface of the eye (microbial keratitis), bleeding inside the eye, damage to the capsule that supports the lens, swelling of the cornea, intraocular lens opacification, swelling in the central area of the retina, remnants of the natural lens being left inside the eye, a detached retina, an uncomfortable or painful eye, droopy eyelids, increased astigmatism, vitreous opacities or floaters, dislocation of the lens implant, glaucoma or double vision. Cataract or NLR surgery may result in blindness, or even the loss of an eye.

This is extremely rare but has been reported in scientific literature.

I understand the above and all of my questions have been answered.

Write your initials here:

As part of the normal healing process it is possible that there may be some swelling in the central part of the retina (the macula). The swelling is called cystoid macular oedema, CMO or CME. This can affect the improvement in vision achieved by the treatment, though in most cases it is a temporary condition that is treated with eye drops or tablets (or both). In rare cases this condition can come back and affect your vision in the long term. If this is the case, you may need more tests and treatment. This may involve extra costs.

I understand the above and all of my questions have been answered.

Write your initials here:

It is impossible to list every complication which could arise from cataract or NLR surgery. We have not told you about risks and complications that are considered to be unforeseeable or extremely rare, or which have not previously been reported. Also, there may be long-term effects that we do not yet know about or cannot expect at the current time.

I understand the above and all of my questions have been answered.

Write your initials here:

We do not recommend that you travel alone for at least two hours after your eye surgery (even if you are travelling a route you know well) or for a week after your eye surgery (where you are travelling a route you do not know well). We cannot predict how you will feel after your eye surgery, and whether you will be able to safely use transport (either public transport or your own transport). For example, you may feel drowsy or disorientated, or have restricted vision.

I understand that if I decide to travel on my own following the treatment, this is at my own risk.

Write your initials here:

To achieve the best result and reduce the risks, I agree to follow the medication regime the surgeon or optometrist prescribes and the aftercare routine described in the information documents.

I agree to follow the aftercare advice you give me relating to protecting my eyes and I will take my medications, including my antibiotic and anti-inflammatory drops, as prescribed.

Write your initials here:

Due to the position of the lens within the eye, it is important that your eye health is checked every year and the thickness of certain layers of the outer surface of the eye (known as the cornea) is measured.

I understand the above, acknowledge your recommendation and agree to have yearly eye examinations.

Write your initials here:

#### **Treating both eyes**

Cataract and NLR surgery is carried out on one eye at a time. If there are no complications, the surgery on the second eye can usually take place within one week of the surgery on the first eye. During the time between the first and second eye treatments, you may notice an imbalance between the two eyes. If this causes you to have unwanted symptoms, these can usually be corrected with a temporary contact lens.

I understand the above and all of my questions have been answered.

| Write your initials here: |  |
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#### **Patient consent**

Your surgeon will help you with the choices in this section. I give my consent to having the following treatment. (Tick the appropriate box.)

I choose to have the following cataract or NLR surgery:
Implant a monofocal lens: Right eye Left eye Implant a multifocal lens: Right eye Left eye

I choose to have cataract or NLR surgery to implant **monofocal lenses** to correct:

Near vision Right eye Left eye Distance vision Right eye Left eye Left eye Distance vision

I choose to have cataract or NLR surgery where the surgeon treating me carries out an all-laser femtosecond procedure:

Yes No Write your initials here:

# Use of medical information

I give permission for you to use information relating to my treatment to help you provide my treatment, review my treatment, give me advice about additional treatment, carry out any additional treatment, and manage your business properly, for example to allow you to keep accurate records and for quality-control purposes.

| Write your initials here: |  |
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I give permission for you to use information relating to my treatment for research purposes, for statistical analysis, in connection with academic and scientific papers, presentations and other publications, and for marketing purposes. I understand that the information relating to my treatment will not reveal my identity.

Write your initials here:

#### **Patient declaration**

We advise you to take enough time to carefully and thoroughly read and understand the information in this document, and the other information you receive during your pre-treatment consultation. If you have not read or understood all of this information, please let us know and do not go ahead with the treatment.

At my consultation my optometrist discussed the risks, benefits and alternatives to cataract and NLR surgery with me.

| Write your initials here: |  |
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consent video which explained the risks and benefits Please confirm you want to go ahead with the surgery by of, and alternatives to, cataract and NLR surgery and writing the following statement in the box below. emphasised the importance of this informed consent document. 'Having considered the information I received at my pre-treatment consultation and the information in Write your initials here: this document, and discussed the risks, side effects, possible outcomes and benefits of treatment with my surgeon, I am happy to go ahead with the surgery. I I received my cataract and NLR terms and conditions understand that I am under no obligation to do so. and informed consent documents at the time of my consultation. Write your initials here: I received my cataract and NLR terms and conditions and informed consent documents more than 24 hours before my surgery. Write your initials here: I confirm that I have taken enough time to carefully and thoroughly read and understand the information in this document and the other information I received during my pre-treatment consultation. I confirm that I have not been placed under any pressure and I do not feel obliged to have treatment. I understand that the decision whether to go ahead with cataract or NLR surgery (whichever applies) is mine alone, and should be based on the information I have received in this document and during my pre-treatment consultation. Your signature: I confirm that all my questions have been answered, and I am satisfied with the answers. I understand that cataract or NLR surgery is an elective procedure (which means Your full name (print): that I can choose whether or not to have this procedure). I understand that there are other ways to correct vision, some which involve surgery and some which do not, but I also understand that there are currently no other effective Your date of birth: ways to correct or restore lost vision that is caused by cataracts. The risks and benefits of treatment have been thoroughly explained to me. Date of your pre-treatment consultation: I give my consent to go ahead with surgery. Date of your signature: Write your initials here: Witness declaration Witness's signature:

Witness's full name (print):

Witness's date of birth:

Date of witness's signature:

Confirmation of declaration

At my consultation I watched the cataract and NLR

## Surgeon declaration

I have discussed the intended procedure with the patient. I am satisfied that the patient has read this informed consent document, and understands it and the risks and benefits of, and alternatives to, the treatment. The patient has told me that I have answered all their questions to their satisfaction. The patient has also told me they are willing to accept the risks associated with the intended treatment, and voluntarily agrees to have cataract or natural lens replacement (NLR) surgery. I agree to accept this patient on the above terms and provide treatment as set out in this document.

| Surgeon's signature:  |  |
|---|--|
| Surgeon's full name (print):  |  |
| Date of surgeon's signature:  |  |
| Surgeon's status (please tick as appropriate): Employee of Optical Express Independent practitioner |  |
| Notes:  |  |

